

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EUNSUNG GLOBAL CORP.,

Petitioner,

v.

HYDRAFACIAL LLC

Patent Owner.

Case No. IPR2025-00445

U.S. Patent No. 9,550,052

DECLARATION OF KARL R. LEINSING, MSME, PE

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: May 13, 2025

By: _____



Digitally signed by Karl R.
Leinsing
Date: 2025.05.13 17:18:43
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Karl R. Leinsing, MSME, PE

1. I, Karl Leinsing, am making this declaration at the request of Patent Owner HydraFacial LLC in support of the Patent Owner's Preliminary Response in the matter of the Inter Partes Review No. IPR2025-00445 of U.S. Patent No. 9,550,052 ("the '052 Patent"). I understand that this declaration is being submitted in this proceeding as Ex. 2001.

2. I am being compensated for my work in this matter at my standard hourly rate for consulting services. My compensation in no way depends on the outcome of this proceeding.

3. In addition to my own knowledge and expertise, I have reviewed and considered the following written materials in conducting the analyses and forming the opinions set forth in this declaration.

Exhibit or Paper No.	Description
2	Eunsung's Petition for Inter Partes Review
1001	U.S. Patent No. 9,550,052
1002	File History for U.S. Patent 9,550,052
1003	January 9, 2025 Declaration of Eric Simon
1004	U.S. Publication No. 2003/0212415 ("Karasiuk")
1005	U.S. Patent No. 5,199,604 ("Palmer")
1006	U.S. Publication No. 2003/0093089 ("Greenberg")

Exhibit or Paper No.	Description
1008	U.S. Patent No. 6,684,880 (“Trueba”)
1020	U.S. Patent No. 4,559,036 (“Wunsch”)
2009	May 13, 2025 Declaration of Vipul Savsani
2030	Hydrafacial Syndeo™ Instruction for Use (IFU), revised May 1, 2023
2031	HydraFacial MD™ Elite™ User Guide, revised November 1, 2023
2032	Hydrafacial™ Allegro MD Instructions for Use (IFU), revised November 06, 2023
2033	HydraFacial MD™ System Owner’s Manual (Tower Owner’s Manual) (2005)
2034	HydraFacial™ Handpiece User Guide, Revised February 19, 2020
2035	HydraFacial Nectre® System Owner’s Manual, Revised May 14, 2008
2036	HydraFacial™ Nectre® System User Manual, Revised January 27, 2009
2037	HydraFacial™ Nectre® System Service Manual, Revised June 12, 2009
2038	Introducing . . . HydraFacial MD™ by Edge Systems Advertisement
2039	HydraFacial™ Rejuvenate Your “Microderm” Business! Advertisement (January/February 2006)
2040	HydraFacial™ Whole New Skin Advertisement
2041	My Life. My Time. My Skin HydraFacial MD™ Advertisement, Dated May 11, 2015
2042	Unique Patented HydraFacial MD® TECHNOLOGY Advertisement (2013)

Exhibit or Paper No.	Description
2043	HYDRAFACIAL™ TOWER SYSTEM Advertisement (2020)
2044	The Elite™ is the Latest HydraFacial System with Advancements to Ensure Your Practice's Success Advertisement (2020)
2045	EXPECT EVERYTHING: Introducing the Brand-New HydraFacial Elite Advertisement (2020)
2046	Expect Everything with the New HydraFacial Elite
2047	The Allegro™ System Advertisement (2020)
2048	Excerpts from the 2003 Bloomsbury Dictionary of Science and Technology 1 st Ed.
2049	Excerpts from the 2004 Bloomsbury English Dictionary 2 nd Ed.
2050	Excerpts from 2005 Collins English Dictionary 7th Ed.
2051	Excerpts from Academic Press Dictionary of Science and Technology
2052	Poiseuille and his law, Anaesthesia, 1976, Volume 31 (J. Pfitzner)
2053	Estimating Water Flow Rates (W.L. Trimmer)
2054	Viscosity of Endodontic Irrigants: Influence of Temperature, Dental Research Journal 2015
2055	Optimization Formula of Antioxidant Cream Vitamin E (α -tocopherol acetate) with Virgin Coconut Oil (VCO), Dian Ermawati, Uswatun Chasanah and Dwi Dwi.
2056	Dixon Valve & Coupling Company. (n.d.). Viscosity chart. https://www.dixonvalve.com/sites/default/files/product/files/brochures-literature/viscosity%20chart.pdf (last accessed May 12, 2025)

To the extent not listed above, I have also reviewed any other materials I discuss or cite herein.

I. QUALIFICATIONS AND PROFESSIONAL BACKGROUND

4. I received a Bachelor of Science (B.S.) degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science (M.S.) degree in mechanical engineering from North Carolina A&T State University in 1995. I am also licensed as a Registered Professional Engineer in the state of New Hampshire (License#: 11437).

5. I have been a medical device engineer since 1992 and have worked extensively with medical device disposables, including syringes of all types, since that date. I have extensive expertise in the mechanical design and manufacturing of medical devices. My areas of expertise include full-life cycle product development of medical devices, including conception, design, prototyping, manufacturing, testing, verification, validation, packaging, bioburden testing, sterility assurance testing, residual testing, biocompatibility, bacterial contamination testing, labeling, clinical trials, regulatory approval, marketing, and sales training.

6. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various medical devices, including cardiovascular, surgical, intravenous, endoluminal, and percutaneous devices. More specifically, I have consulted in the development of various drug delivery devices, such as IV

pumps, peritoneal dialysis pumps, auto-injectors, pen injectors, syringes, safety syringes, disinfecting caps, stop-cock valves, urinary catheter kits that include either bags or metered containers, IV valves, catheter dressing designs that use a burst-type foil pouch that releases an antiseptic, subcutaneous ports, catheters, wound closure device, among others. In many of these applications, vaporized hydrogen peroxide, ethylene oxide (EtO), gamma irradiation, autoclave, or E-beam sterilization methods were used to sterilize the medical devices.

7. Previously, from 2005 to 2006, I worked as a Director of Biomedical Engineering at Mitralign, Inc., developing implants for heart valve repair. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, Inc., developing fixation devices for abdominal aortic aneurysm repair as well as laparoscopic devices for stapling and sutures.

8. From 1992 to 2002, I worked as a Senior Principal Design Engineer at IVAC, which was a subsidiary of Eli Lilly & Company. There, I developed a number of medical drug infusion products, including disposable sets and components, IV tubing and syringe pump systems, injection systems, vial adapters, syringes, solution bags and containers, and needle-free valves for the delivery of drugs. My work involved both the conception and manufacturing of these devices, including both EtO and gamma irradiation sterilization of disposable medical devices such as syringes and male luer caps. During this time, I was the sole inventor

of the SmartSite® Needle-Free Valve for intravenous infusion pumps and disposables. I was also involved in the development of a dual-acting pen injector, capable of dispensing both long-term and short-term insulin, for Eli Lilly (parent company of my employer IVAC). In addition to my extensive involvement with the design team for the entire device, my work focused on the development of the disposable needle, valve mechanism, and adapters that attached to the distal end of the device.

9. I am a named inventor of over 41 patents, all of which relate to the medical device field. I have previously lectured on the product design and manufacturing process of medical devices. I was also named Chairman of the Medical Device and Manufacturing Conference in 2014 for the development process of medical devices.

10. I have personal knowledge of the matters set forth in this declaration and, if called upon as a witness, would testify competently thereto. I have used my education and my years of experience working in the field of mechanical engineering and medical device design, and my understanding of the knowledge, creativity, and experience of a person of skill in the art in performing the analysis expressed in this declaration.

11. My *curriculum vitae* lists additional information about my professional background and qualifications. Ex. 2002 is a true and correct copy of my *curriculum vitae*.

II. RELEVANT LEGAL STANDARDS

12. I am an engineer by training and profession. The opinions I express in this declaration involve the application of my knowledge and experience to the evaluation of the '052 Patent and certain prior art to that patent. My knowledge of patent law is that of a lay person. Therefore, counsel for Patent Owner provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of the principles related to patentability that I must apply, and have applied, in conducting my analyses and reaching the opinions set forth in this declaration.

13. I understand that, in assessing the patentability of a patent claim, the Patent Office generally construes claim terms by giving them their ordinary and customary meaning, as they would have been understood by a person of ordinary skill in the art (“POSITA”) at the time of the invention in view of the intrinsic record (patent specification and prosecution history). However, I understand that the inventors may, in the patent specification, expressly define a claim term to have a meaning that differs from the term’s ordinary and customary meaning. I also understand that the inventors may disavow or disclaim certain claim scope, thereby

departing from the ordinary and customary meaning, when the intrinsic record demonstrates that a clear and unambiguous disavowal or disclaimer has occurred. I understand that extrinsic evidence, such as relevant technical literature and dictionaries, may be useful in ascertaining how a POSITA would have understood a claim term, but the intrinsic record is the primary source for determining the meaning of claim terms. For the purposes of this review, and to the extent necessary, I have interpreted each claim term in accordance with the principles set forth in this paragraph.

14. It is my understanding that a claim is unpatentable as “anticipated” under 35 U.S.C. § 102 if a single prior art reference discloses every limitation of the claim, arranged as in the claim. I understand that a prior art reference does not anticipate a claim, however, when it discloses multiple, distinct teachings that a person of ordinary skill in the art might somehow combine to achieve the claimed invention. I understand that anticipation has not been alleged in the Petition, and, thus, is not at issue in this proceeding.

15. I understand that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I also understand that an obviousness analysis takes into account the following factors, which are sometimes referred to as the Graham factors: (1) the scope and content of the prior art, (2) the

differences between the claimed subject matter and the prior art, (3) the level of ordinary skill in the art at the time of the invention, and (4) “objective indicia of non-obviousness,” also referred to as secondary considerations of non-obviousness. Those objective indicia include considerations such as whether a product covered by the claims is commercially successful due to the merits of the claimed invention, whether there was a long felt need for the solution provided by the claimed invention, whether others failed to find the solution provided by the claimed invention, whether others copied the claimed invention, and whether there was acceptance by others of the claimed invention as shown by praise from others in the field.

16. In determining the scope and content of the prior art, it is my understanding that it is appropriate to consider a prior-art reference in an obviousness analysis if it falls within the field of the inventor’s endeavor or is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have come to an inventor’s attention in considering his or her problem.

17. To assess the differences between prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This “as a whole” assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would

have selected the elements from the prior art and combined them in the claimed manner.

18. I also understand that in an obviousness analysis, a patent challenger must demonstrate with evidence that a POSITA would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the POSITA would have had a reasonable expectation of success of doing so.

19. I understand that an assessment of what a reference discloses or teaches—for purposes of an anticipation analysis or an obviousness analysis—must be conducted from the perspective of a POSITA at the time of the invention.

III. LEVEL OF ORDINARY SKILL IN THE RELEVANT ART

20. The relevant field of art is skin treatment, and more specifically apparatuses and methods of treating a person's skin, as described in the '052 Patent.

21. I understand that the level of ordinary skill in the art for the '052 Patent is determined as of December 30, 2005, which is the earliest effective filing date of the patent. I also understand that Eunsung has not alleged that the '052 Patent is not entitled to the December 30, 2005 effective filing date.

22. In my opinion, a POSITA for the '052 Patent would have a degree in science or engineering plus a minimum of three years of experience in the medical device industry. Alternatively, a product designer could have an additional two

years of experience in the industry in lieu of a formal science or engineering degree. The POSITA would also consult with a physician as needed to understand the medical implications of the disclosed device, including the effect of the device on the skin.

23. I applied the above definition of a POSITA in my analysis set forth in this declaration. I understand the capabilities of a POSITA as of December 2005. Based on my training and experience, I understand the level of knowledge and skill that a POSITA would have possessed in December 2005 and am familiar with what a POSITA would have understood regarding microdermabrasion and hydrodermabrasion at the relevant time. In fact, I was a POSITA at the relevant time.

24. I understand that Eunsung has proposed the following definition of a person of ordinary skill in the art (a “POSITA”) with respect to the ’052 Patent:

A person having ordinary skill in the art (POSITA) at the time of the alleged invention would have had an undergraduate degree (B.S.) in Mechanical Engineering or equivalent knowledge, training, or experience, with two years of work experience in the design of mechanical products, design of fluidic systems, and/or the design of devices intended for medical or cosmetological applications. Additional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above.

Pet., 2-3.

25. At this time, I do not address the deficiencies in Eunsung's definition of the level of skill in the art but reserve the right to raise any such deficiencies in a future declaration or testimony. Under either parties' definition, it is my opinion that the claims of the '052 Patent would not have been obvious as Eunsung and Mr. Simon have alleged.

IV. CLAIM CONSTRUCTION

26. I understand that claim terms are generally given their plain and ordinary meaning in view of the specification. In my view, no express claim construction that differs from the plain and ordinary meaning is necessary to assess the issues I was asked to analyze. However, below, I have specifically addressed and applied the plain and ordinary meaning of the term "manifold" to address an argument Eunsung has made with respect to the disclosure of the Palmer reference.

V. PATENTABILITY OF THE '052 PATENT OVER THE PRIOR ART

27. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Karasiuk combined with other prior art, as more fully explained below. Eunsung relies on Karasiuk as its primary reference in all Grounds presented (1A, 1B, 1C, 1D, 1E, and 1F). In Ground 1A, Eunsung combines Karasiuk with Palmer to allege that independent claims 1 and 11, and dependent claims 4-10, 12, and 15-17 would have been obvious. Pet., 1. As I

explain below, it is my opinion that Eunsung's combination of the Palmer system with the Karasiuk system would fundamentally alter the operation of each system and render the Karasiuk device inoperable in multiple ways.

28. In Grounds 1A-1C, Eunsung relies on Palmer as allegedly disclosing the claimed "manifold," but the Palmer component Eunsung points to is not a "manifold." In Ground 1B, Eunsung relies on Trueba for computing device limitations. In Ground 1C, Eunsung relies on Mercier for a handpiece assembly.

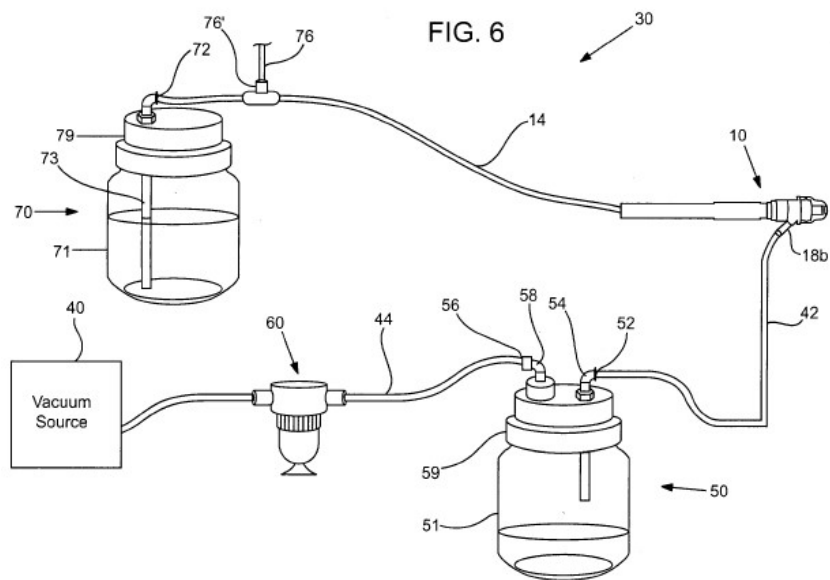
29. In grounds 1D-1F, Eunsung relies on Wunsch as disclosing the claimed "manifold" in an attempt to cure the deficiencies of Palmer. In Ground 1E, Eunsung relies on Trueba for computing device limitations. In Ground 1F, Eunsung again relies on Mercier for a handpiece assembly.

B. The Cited References

1. Karasiuk¹

30. As shown in Figure 6 below, Karasiuk is a device that draws liquid from just one container during a treatment.

¹ I recognize that Karasiuk describes the disclosed device as a "microdermabrasion device." However, I understand that Karasiuk differs from traditional microdermabrasion because the device is not limited to using only solid dry abrasive particles.



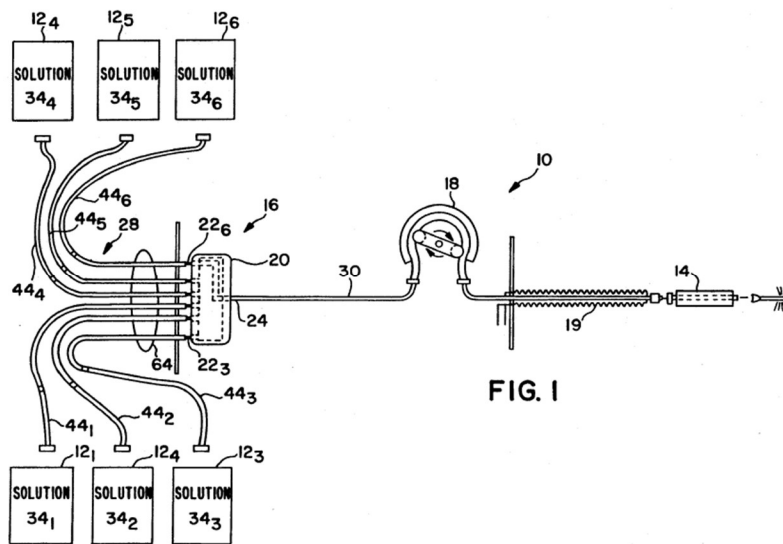
Ex. 1004, Fig. 6, [0014], [0020].

31. In my view, Karasiuk does not disclose a manifold as part of a console—or a manifold at all—in fluid communication with a first fluid container and at least a second fluid container and a handpiece. Nothing in Karasiuk suggests separately storing and automating the application of different treatment fluids in a single treatment. At most, Karasiuk lists different solutions, suspensions, or compounds that can be contained “alone or in combination” in Karasiuk’s single reservoir 70. *Id.*, [0061].

2. Palmer

32. Palmer is an irrigation system used in periodontal dental procedures. Ex. 1005, 1:10-15. As such, Palmer delivers “pulsed jets” of treatment solution at constant pressure and substantially constant volumetric flow rate to the treatment

area in the patient's mouth. *Id.*, 11:17-23 (pressure of 25 psi and flow rate of 22-25 mL/minute). Palmer employs a peristaltic pump 18 located upstream of handpiece 14 to generate the pulsed jets of solution, as shown in Fig. 1.



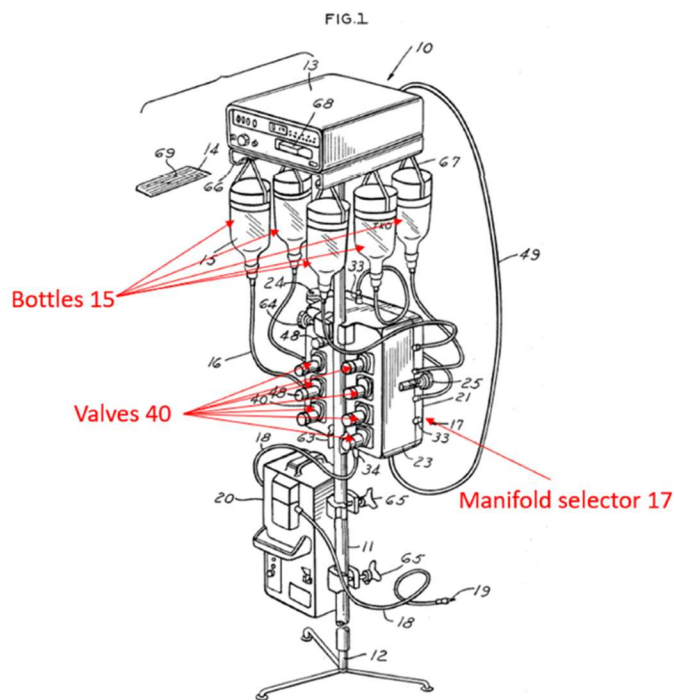
Id., Fig. 1.

33. The handpiece sprays the pulsed jet directly at a treatment site in the patient's mouth to irrigate it with the needed solution. *Id.*, 3:15-26. Unlike a skin treatment system, Palmer is a one-way irrigation system that lacks any mechanism to vacuum the spent solution from the patient's mouth and back through the handpiece. Palmer uses a peristaltic pump "as a natural check valve since it cannot aspirate solution back into the cannula" of the handpiece. *Id.*, 11:32-33.

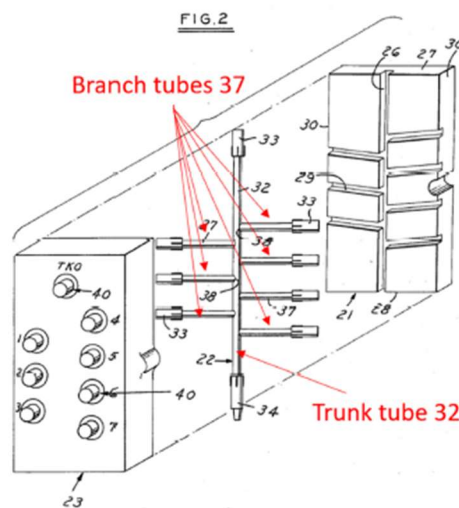
34. In my view, Palmer—like Karasiuk—does not disclose a manifold.

3. Wunsch

35. Wunsch is a system for sequentially dispensing multiple intravenous (IV) solutions from multiple solution sources through a single catheter. Ex. 1020, 5:18-22. Each solution source is connected to a distinct branch (e.g., branch tubes 37) of a manifold (e.g., combination of trunk tube 32 and branch tubes 37), with flow through each branch controlled by a valve selector that actuates valves mounted on a manifold plate. *Id.*, 7:49-52. These valves are individually actuated by electronically operable motors or solenoids. *Id.*, 6-18-26.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

Pet., 69, 71.

36. The “manifold” (e.g., combination of trunk tube 32 and branch tubes 37) from Wunsch cannot, independently, control the flow of treatment of material—

and Eunsung agrees with this statement. *See* Ex. 1020, 4:1-10, 7:17-56; Pet., 70 (“In operation, by activating an individual valve 40, the user can selectively connect a chosen bottle 15 to the trunk tube 32 for delivery.”). The “manifold” of Wunsch (*i.e.*, the trunk tube 32 and branch tubes 37) would result in an open system with uncontrolled, free-flowing liquid from each solution source.

37. A volumetric infusion pump meters the dispensed quantity of each solution. *Id.*, 6:7-13. The sequence and timing of solution delivery is governed by a sequencer-timer, which automatically and successively actuates each valve in accordance with a predetermined program (*e.g.*, stored on a program card). *Id.*, 5:25-35, 51-55.

4. Trueba

38. Eunsung adds Trueba in Ground 1B and 1E for dependent claims having computing device limitations, and for claim 6 already addressed in Ground 1A. Pet., 39, 48-56. Trueba involves a jet dispenser that combines Hewlett-Packard’s inkjet technology with pharmaceutical administration. Ex. 1008, 1:7-12.

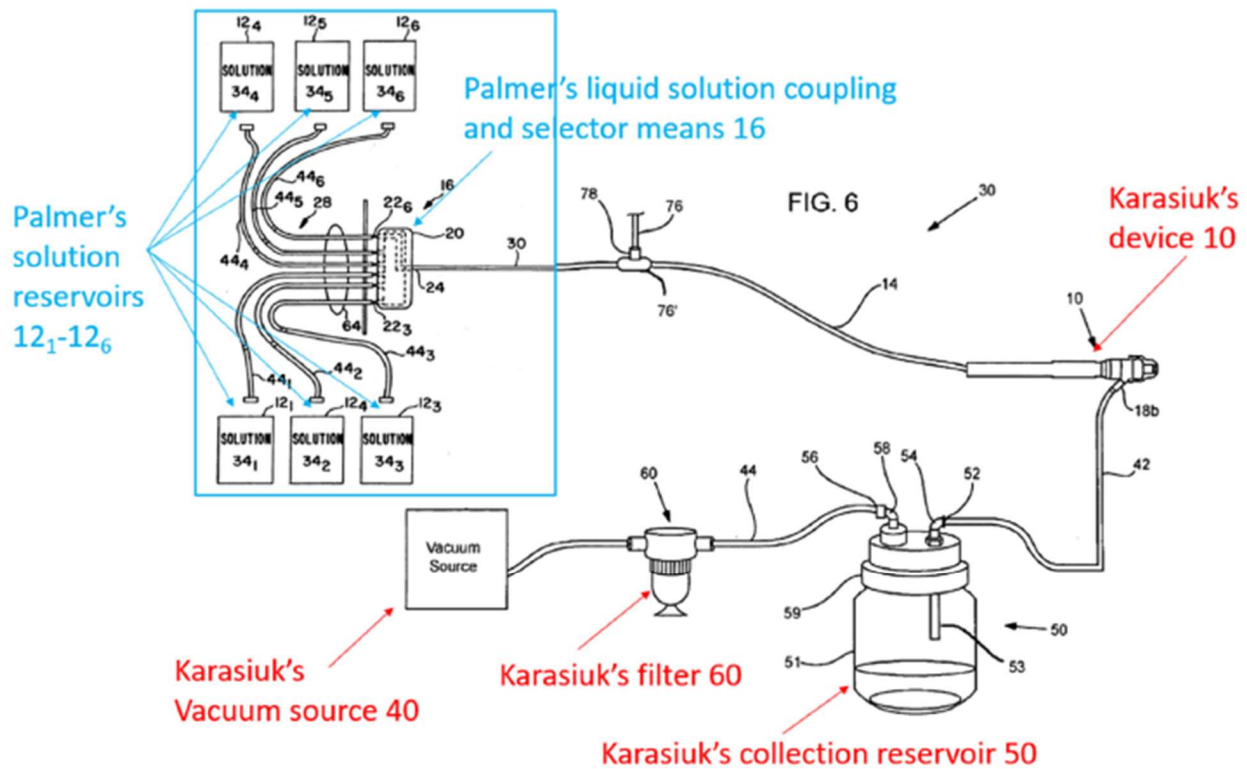
C. All Grounds: The Karasiuk-Palmer Combination Renders Karasiuk’s Device Inoperable

39. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Karasiuk and Palmer combined with other prior art, as more fully explained below.

40. In my opinion, Eunsung's proposed combination of the Karasiuk and Palmer systems would render Karasiuk's system inoperable, because the resulting system: (1) has a vacuum source with a breather line that prevents material from flowing from the reservoirs; (2) has a tube diameter that is so small it prevents flow of higher viscosity treatment materials; and (3) lacks Palmer's peristaltic pump, leading to the unrestricted flow of liquid from the reservoirs.

1. Karasiuk-Palmer's Vacuum Source With a Breather Line Prevents Drawing Material from the Reservoirs

41. In Eunsung's proposed combination of the Karasiuk and Palmer systems, Eunsung contends that "Karasiuk's vacuum source would be used to pump treatment solutions from Palmer's multiple fluid containers and collect waste/debris." Pet., 8. That is, Eunsung removes Palmer's peristaltic pump from Palmer's system and instead relies on Karasiuk's vacuum source 40 downstream of the handpiece to act as the vacuum source in the combined device. Eunsung depicts this combination of Palmer's Fig. 1 and Karasiuk's Fig. 6 as "Karasiuk, Modified FIG. 6".

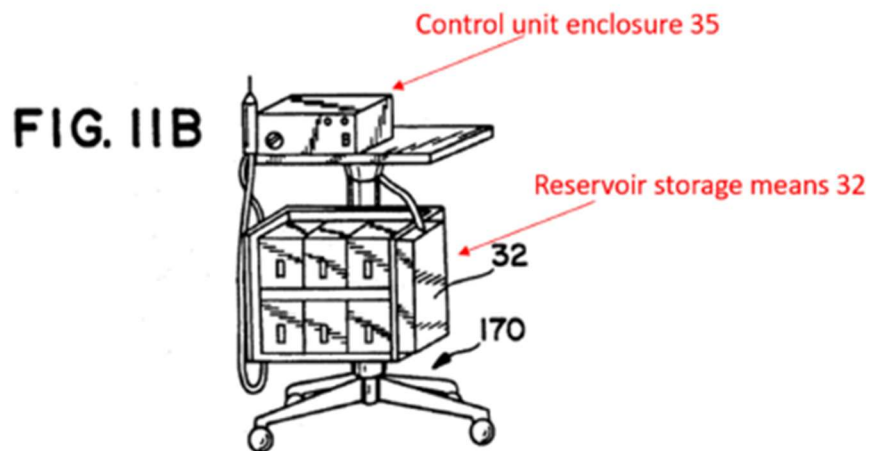


Karasiuk, Modified FIG. 6

42. As can be seen in Eunsung's combination figure, "Karasiuk's tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Palmer's second tubing means 30 to achieve benefits resulting from selection of different treatment solutions." Pet., 8, 24, 30. Here, Eunsung has positioned Karasiuk's breather line 76 upstream of Karasiuk's device 10 (the handpiece) and downstream of Palmer's liquid solution coupling and selector means 16 and Palmer's solution reservoirs 12₁ - 12₆. *Id.* I note that Eunsung also contends that this arrangement "achieve[s] benefits resulting from selection of different treatment solutions." Pet., 8, 24, 30.

43. Karasiuk discloses that its breather line 76 “includes an adjustable valve 78 or other means for varying an amount of air that is allowed into tube 14,” which “allows the amount of vacuum to be adjusted for a given fluid.” Ex. 1004, 7:19-24.

44. Eunsung’s Karasiuk-Palmer combination also involves adoption of Palmer’s “mobile cart 170” for allegedly providing “increased portability and/or organization.” Pet., 7. In Eunsung’s combination, Palmer’s mobile cart 170 houses the claimed multiple containers (Palmer’s “solution reservoirs 12₁ - 12₆”) in the “reservoir storage means 32” on the bottom of the mobile cart 170 underneath the system components in the “control unit enclosure 35” on the shelf above:



Palmer, FIG. 11B

Pet., 14.

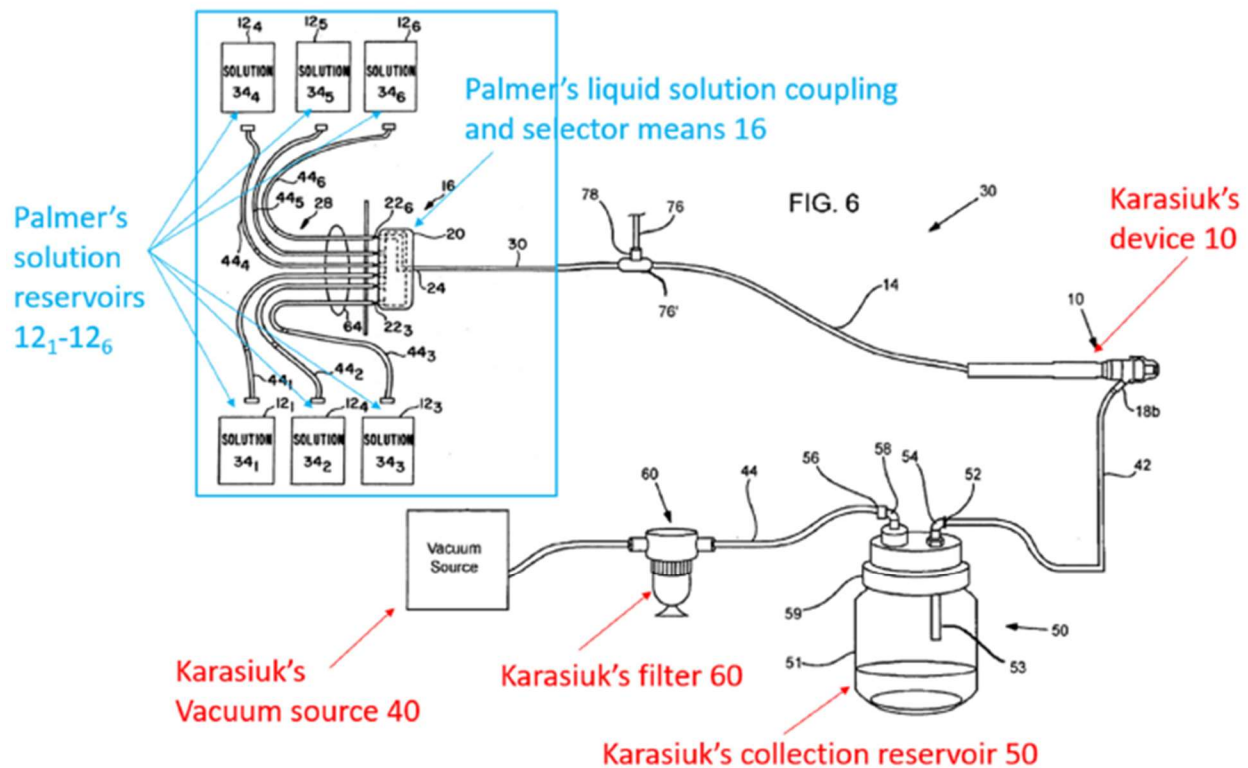
45. In the Karasiuk-Palmer combination, Palmer’s solution reservoirs 12₁ - 12₆ are necessarily located below Karasiuk’s breather line 76 and the handpiece 10. In this configuration, Karasiuk’s vacuum source drawing only air through the

breather line 76 along tube 14. The Karasiuk-Palmer combination would never be able to provide any vacuum force to draw material from Palmer's solution reservoirs to the handpiece. This is because air flow will take the path of least resistance and suck air from the breather line 76 as described by Karasiuk instead of fluid from Palmer's solution reservoirs 12 in Eunsung's proposed combination. This is like having a crack in a drinking straw. Thus, in my opinion, the Karasiuk-Palmer combination (small tubing with air vent) changes the basic principles under which Karasiuk was designed to operate and renders it inoperable. Karasiuk alone, when using the vent on the liquid side of the system, is not enabled. This is the "cracked drinking straw" problem and neither the petition nor the combinations with other prior art resolve this issue. In my view, Eunsung's proposed arrangement clearly defeats the alleged purpose behind the combination of "achiev[ing] benefits resulting from selection of different treatment solutions." Thus, a POSITA would not have had a motivation to combine Karasiuk with Palmer.

2. Karasiuk-Palmer's Tube Diameter Prevents Flow of Treatment Material

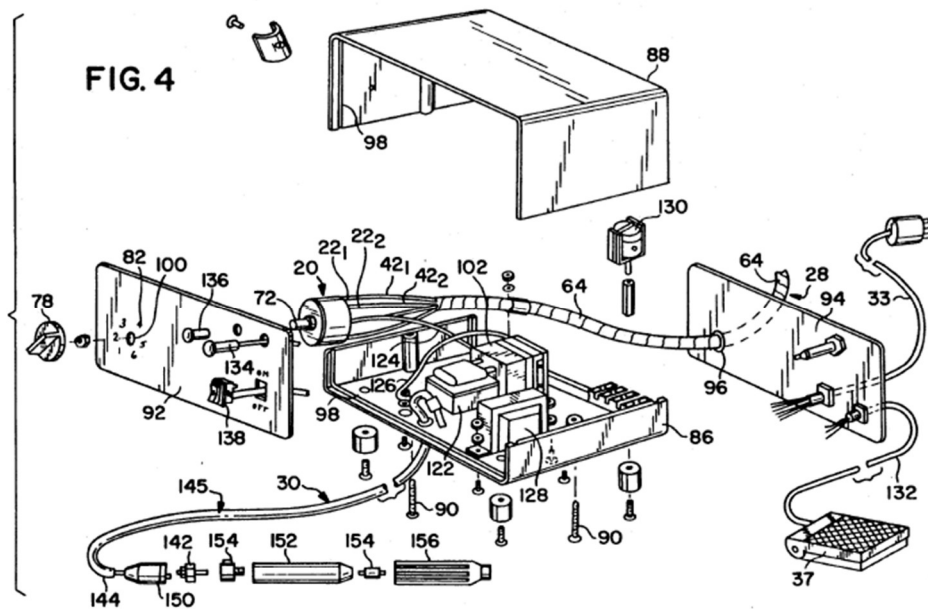
46. In my opinion, Palmer's small-diameter tubing renders the combined Karasiuk-Palmer device inoperable.

47. As explained above, for the Karasiuk-Palmer combination, Eunsung relies on Palmer for its liquid solution coupling and selector means 16 and solution reservoirs 12.

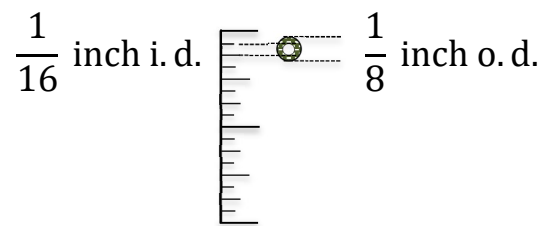


Karasiuk, Modified FIG. 6

Pet., 8, 16. The detailed version of the liquid solution coupling and selector means 16 is Palmer's control unit enclosure 35, an explode view of which is shown in Fig. 4 of Palmer:



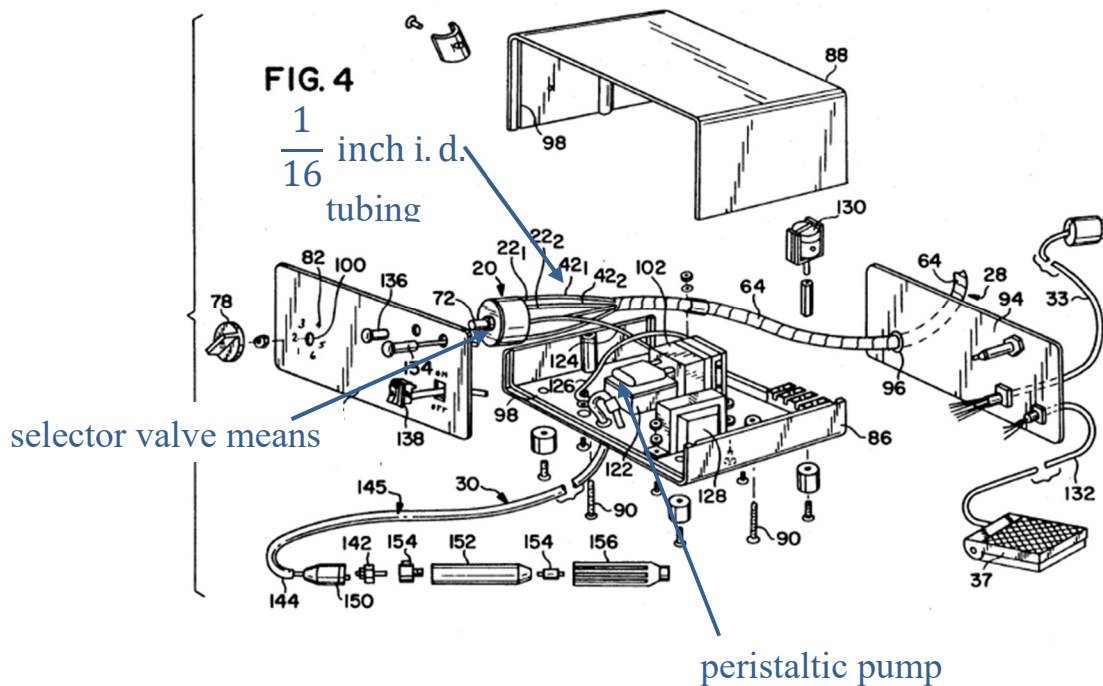
48. Palmer discloses that the system uses tubing with an outside diameter of $1/8^{\text{th}}$ inch and an inside diameter of $1/16^{\text{th}}$ inch in the six tubes 42 running between the solution reservoirs 12 and the selector valve means 20 in the control unit enclosure, and in tubing 126 running from the control unit enclosure 35 to the handpiece 14. *See Ex. 1005, 7:21-24, 9:17-19, 9:40-43.* Below is an image I have prepared to show the cross-sectional diameter of Palmer's tubing on the scale of an 8 1/2 x 11-inch sheet of paper:



49. In my opinion, an extremely small tube diameter of 1/16th inch is appropriate in Palmer's system given that Palmer's system is designed to produce high-velocity spray to irrigate a patient's mouth with a relatively high-pressure output. Ex. 1005, 2:32-36. Further, Palmer's tubing is appropriately small so that it is flexible and compact in the bundle of six tubes that extend from the control unit enclosure 35 to the reservoir storage means 32, which houses the solution reservoirs.

50. Palmer states that its system is designed to deliver the pulsed jets of irrigating solution at a pressure of 22-25 psi, with a flow rate of only 22 to 25 mL per minute. *Id.*, 11:17-23. At that flow rate, it would take 40-45 minutes of continual spraying to use all the contents of the 1000 mL containers disclosed in Palmer. *Id.*, 5:26-30.

51. In my opinion, Palmer's system supports the use of such small tubing because Palmer's peristaltic pump is located directly adjacent to the selector valve means 20 to generate pressure to draw the liquids from the containers. This is shown in Fig. 4:



Ex. 1005, Fig. 4. Additionally, Palmer also uses low-viscosity rinse solutions, minimizing any resistance from the liquid flowing through the tubing. *Id.*, 5:52-64.

52. In my opinion, Palmer's small-diameter tubing renders Eunsung's proposed combination of Karasiuk and Palmer inoperable.

53. As discussed above, Eunsung's proposed combination removes Palmer's peristaltic pump and replaces it with Karasiuk's vacuum source 40, which is located at the end of the fluid path, downstream of the handpiece 10 and collection reservoir 50. As a general matter, the pressure drop exhibited along a length of tubing is directly proportional to the length of the tubing. Thus, in Eunsung's modification, the added distance between the vacuum source and Palmer's solution

reservoirs 12 results in increased pressure loss (i.e., increased head loss) at the solution reservoirs 12.

54. Furthermore, in fluid dynamics, the pressure drop (ΔP) across a pipe is strongly influenced by the pipe's internal diameter. For laminar flow of a Newtonian fluid in a straight circular pipe, the relationship is governed by the Hagen-Poiseuille equation:

$$\Delta P = \frac{8\mu L Q}{\pi r^4}$$

where μ is the dynamic viscosity of the fluid, L is the length of the pipe, Q is the volumetric flow rate, and r is the pipe radius. See Ex. 2052, 1. As the equation above indicates, increase in tubing length L and use of higher viscosity solutions used in hydrodermabrasion procedures will increase the pressure drop or resistance to flow. Moreover, as the equation illustrates, even a modest decrease in radius would result in a dramatic increase in pressure loss because the pressure drop is inversely proportional to the fourth power of the radius of the pipe (e.g., halving the radius of a pipe would cause the pressure drop to increase 16-fold).

55. Furthermore, maintaining a constant volumetric flow rate (Q) while reducing pipe diameter necessarily increases fluid velocity. This relationship is governed by the following equation, $Q = A \cdot v$, where A is the cross-sectional area

(which scales with the square of the pipe's diameter) and v is the flow velocity. *See* Ex. 2053, 1. Accordingly, even modest reductions in pipe diameter result in substantial increases in velocity. For instance, halving the pipe's radius reduces the area by a factor of four, thereby quadrupling the velocity to maintain the same flow rate.

56. I understand that certain dental applications, such as those involving irrigant solutions as in Palmer, benefit from high fluid velocity. I also understand that these dental procedures typically do not require high volumetric flow rates. In contrast, hydrodermabrasion procedures generally relatively low volumetric flow rates (to conserve expensive serums) and derive little to no benefit from increased fluid velocity.

57. Thus, a small decrease in pipe diameter can lead to a disproportionately large increase in pressure drop. In my view, this highly non-linear dependence is critical in the design of piping systems, especially when dealing with high-viscosity fluids or long flow paths.

58. In my opinion, Palmer's use of small-diameter tubing, in conjunction with the distance between Karasiuk's vacuum source 40 and Palmer's solution reservoirs 12, and the presence of breather line 76—which prevents the vacuum source from drawing sufficient suction at the reservoirs 12 as I discussed above—

would severely inhibit the generation of suction at the solution reservoirs 12 in Eunsung's combined Karasiuk-Palmer system.

59. Karasiuk also discloses using lotion—often mixed with solid abrasive particles—as the treatment material in the reservoir 70. *See* Ex. 1004, ¶¶[0059]-[0061]. It is well understood and documented that lotions have a significantly higher viscosity than the rinse solutions used in Palmer's system. *See* Ex. 2054, 6 (dental irrigants having viscosities between 35.5 cP and 182.1 cP); *see also* Ex. 2055, 1 (showing vitamin E creams with viscosities between 12,000-26,000 cP); *see also* Ex. 2056, 1 (showing water having a viscosity of 1 cP, face cream at 10,000 cP, and hand cleaner at 2,000 cP).

60. In my opinion, if a lotion were used in Palmer's solution reservoirs 12, it would encounter significant frictional losses (or drag) due to the narrow 1/16th inch diameter tubing connecting the reservoirs 12 to the selector valve means 20 within the control unit enclosure 35.

61. In my opinion, Palmer's tubing is so small that it does not permit meaningful flow of Karasiuk's treatment liquid to the handpiece under vacuum pressure from Karasiuk's vacuum source 40. And even if some fluid were to reach the handpiece, the resulting volumetric flow rate would be unacceptably low for effective use in a skin treatment.

3. Removing Palmer's Peristaltic Pump from Karasiuk-Palmer Leads to Uncontrolled Flow of Liquid from the Reservoirs

62. In my opinion, Eunsung's Karasiuk-Palmer system—by removing Palmer's peristaltic pump 18 and substituting Karasiuk's vacuum source 40 downstream of the handpiece—introduces another fatal flow into the resulting combination, rendering it inoperative for its intended purpose.

63. Palmer's peristaltic pump 18 is located downstream of the selector valve means 20 and, in my view, acts as a valve, preventing liquid from flowing from the solution reservoirs when the peristaltic pump is inactive. *See* Ex. 1005, 11:30-34 (Palmer explaining that its peristaltic pump “serves as a natural check valve.”). Additionally, as I explain below, Palmer's selector valve means 20, which Eunsung relies on for the claimed manifold, serves as an uninterrupted pathway from the selected solution reservoir 12.

64. In my opinion, removing Palmer's peristaltic pump from Eunsung's Karasiuk-Palmer combination system would leave the system without a mechanism to control the flow of liquids from the solution reservoirs. Thus, even if the system did not have the issues associated with the breather line 76 and restricted diameter tubing discussed above, Eunsung's combination would result in the material in the selected solution reservoir flowing uncontrolled to or from the selected solution reservoir, even without activating the vacuum source (*i.e.*, the fluid would flow back

to the reservoir, gravity would cause fluid to flow out, or the fluid would flow out because of syphoning). Thus, once again, these alterations would render the system inoperable. Moreover, the Eunsung's proposed combination would be unable to meet the "control a flow" limitation in claims 1 and 11 of the '052 Patent. Therefore, Eunsung cannot meet its burden of showing that any claims of the '052 patent would have been obvious over the cited prior art.

D. Grounds 1A-1C: Palmer Does Not Disclose the Manifold Limitations

65. Every ground in the Petition relies on a combination of Karasiuk and Palmer (Pet., 1), but this combination, in my opinion, fails to disclose a limitation required by all claims—namely, a "manifold." Both independent claims of the '052 patent recite a manifold in fluid communication with multiple fluid containers. Limitation [1.1] in claim 1 recites "a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container." Similarly, limitation [11.1] in claim 11 recites "a manifold in fluid communication with at least two fluid containers."

66. In Grounds 1A-1C, Eunsung relies on Palmer's "selector valve means 20" as allegedly satisfying the manifold limitations. In my opinion, Palmer's selector valve means 20 cannot meet these limitations under the well-understood meaning of "manifold." In the Petition, Eunsung recognizes that under the ordinary

meaning of the term, a “manifold” has multiple openings. Palmer’s selector valve means 20, in contrast, is limited to a one-input-one-output connection. In my opinion, Eunsung’s argument contradicts its own definition of “manifold,” finds no support in Palmer, and ultimately relies impermissible hindsight.

1. The Ordinary Meaning of the term “Manifold”

67. The term “manifold” is common in the mechanical arts. A person of ordinary skill in the art would understand that a manifold is a pipe or closed space in a machine that has multiple openings, allowing liquids and gases to enter and leave. This understanding is consistent with dictionary definitions and engineering texts:

- “a system of pipes for a fluid from single input to multiple output or multiple input to single output.” Ex. 2048, 3.
- “a chamber or pipe with several openings for receiving or distributing a fluid or gas, e.g. the intake or exhaust manifolds of an internal combustion engine.” Ex. 2049, 3.
- “a chamber or pipe with a number of inlets or outlets used to collect or distribute a fluid.” Ex. 2050, 3.
- “a pipe or chamber that has multiple openings to allow passage of a fluid.” Ex. 2051, 3.

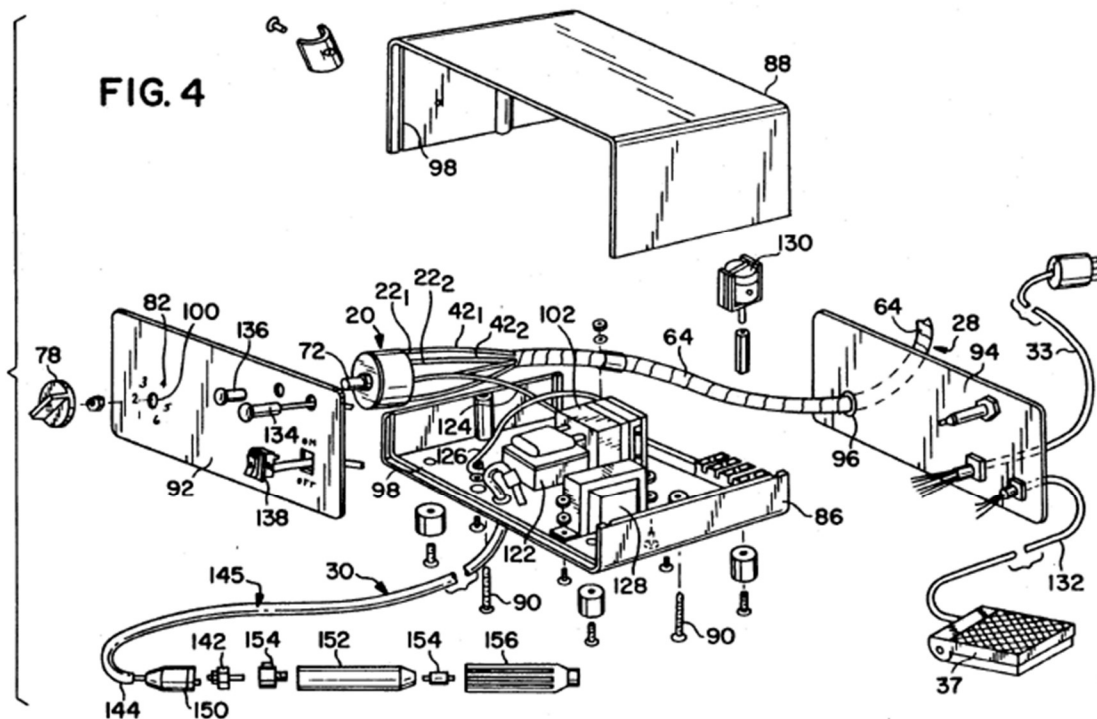
68. In accord with this commonly understood meaning, Eunsung and its expert, Mr. Simon, cite a mechanical engineering dictionary that defines “manifold” as “a chamber or pipe with many openings.” Pet., 15 (citing Ex. 1029, 5); *see also* Ex. 1003, ¶104 n.1 (Ex. 1029, 5).

69. Thus, it appears there is no dispute regarding the ordinary meaning of “manifold” or the fact that it applies to the claims of the ’052 Patent.

2. Palmer’s Selector Valve Means 20 Is Not a Manifold

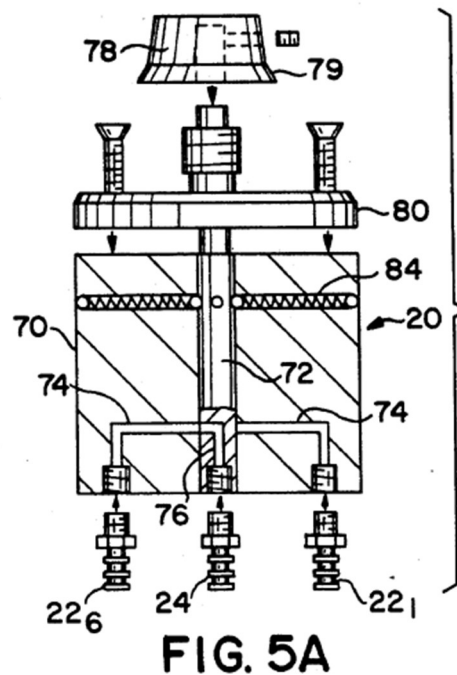
70. Eunsung asserts that the manifold limitations are met by Palmer’s “selector valve means 20.” *See* Pet., 13-19, 44. In my opinion, Eunsung’s argument fails under the well understood meaning of “manifold” adopted by Eunsung.

71. Palmer’s Fig. 4 shows that the selector valve means 20 is a rotary-type valve located in the control unit enclosure 35:



Ex. 1005, Fig. 4.

Palmer's Fig. 5A provides a more detailed view of the selector valve means 20:

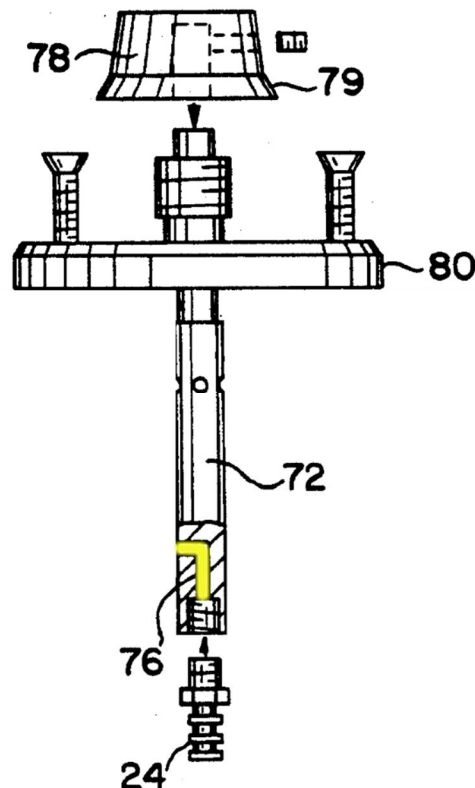


Ex. 1005, Fig. 5A.

72. Palmer describes the selector valve means 20 as having a one-input-to-one-output arrangement: “means for coupling a selected *one* of the inputs 22 to *the* output 24.” Ex. 1005, 5:1-9. The selector valve means 20 includes a main body 70 and a central cylinder core or stem 72, which is mounted within the main body 70. *Id.*, 8:6-8. The central cylinder core 72 has a “liquid outlet passage 76,” which consists of a single inlet and a single outlet: “A liquid outlet passage 76 is formed in the rotatable core 72 having *one end opening* into the selector valve output port 24

and another end opening onto the cylindrical core surface in the plane of the inner ends of passages 74.” *Id.*, 8:13-18.

73. The outlet passage 76’s single-input-to-single-output connection within the core 72 is shown in yellow in the excerpt from Fig. 5A below:



Id., Fig. 5A excerpt (annotated).

74. When a user rotates the knob 78 on the front of the selector valve means 20, the central cylinder core 72 is “rotated until the end of the outlet passage 76 communicates with the particular inlet passage 74 corresponding to the inlet coupled to the desired irrigating solution.” Ex. 1005, 8:45-48. “For example, when the knob is rotated so that the pointer 78 indicates the indicia designated ‘6’, the outlet passage

76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.” Ex. 1005, 8:48-53.

75. In my opinion, this configuration permits only a single input-to-output connection at any given time, as illustrated in Fig. 5A below. In the annotated figure, the selector valve means 20 connects the inlet port 22₆ to the outlet passage 76 (the connected path shown in green), while the inlet port 22₁ is disconnected and physically blocked from the outlet passage 76 (the disconnected path shown in red):

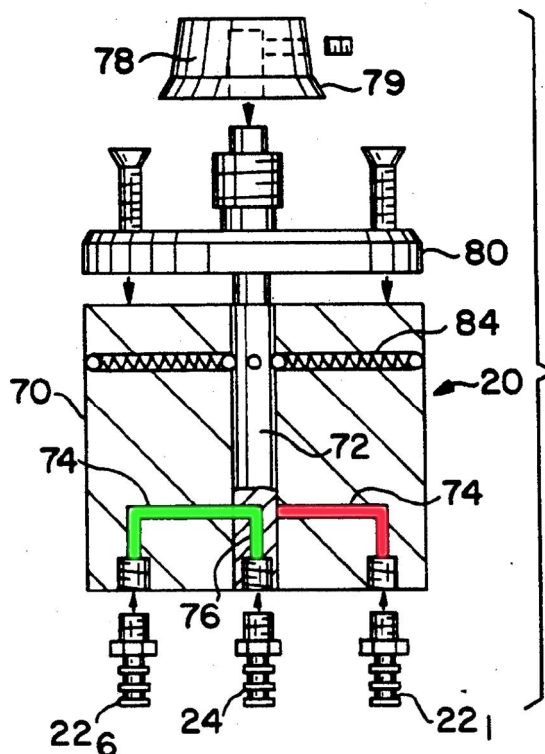


FIG. 5A

Ex. 1005, Fig. 5 (annotated). This annotated figure further illustrates that the remaining inlet ports—22₂, 22₃, 22₄, 22₅—are disconnected to, and effectively isolated from the outlet passage 76.

76. In my opinion, Palmer’s design is fundamentally distinct from a manifold, which, according to Eunsung’s own cited definition, requires “a chamber or pipe with many openings.” As such, it is my opinion that Palmer’s selector valve means 20 does not meet the manifold limitation in independent claims 1 and 11, and the Petition fails to establish otherwise.

77. In my opinion, neither the Petition nor the expert declaration identify shortcoming in Palmer’s selector valve means 20 that would justify replacing it. Pet., 19-22; Ex. 1003, ¶¶110-113. At most, the Petition contends a POSITA would have selected a manifold because “it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input.” Pet., 21. However, Palmer’s selector valve means 20 already eliminates manual connections, and the Petition and expert declaration fail to explain how a manifold could possibly simplify Karasiuk’s handpiece design.

78. In my opinion, a device that selectively connects one input to one output, like Palmer’s selector valve means 20, is not equivalent to “a chamber or pipe with many openings.” In my view, replacing one with the other would require significant unaddressed structural and functional changes to accommodate the manifold’s many openings—this is not a simple substitution.

E. Grounds 1D-1F: Wunsch Does Not Cure Palmer's Deficiencies

79. In Ground 1D, Eunsung adds Wunsch to the combination of Karasiuk and Palmer in an attempt to cure Palmer's deficiencies. Pet., 1, 68-85. Eunsung asserts that a POSITA would have entirely replaced Palmer's liquid solution coupling and selector means 16 with Wunsch's manifold selector and sequencer-timer. Pet., 1, 71. In my opinion, the proposed modification is illogical and clearly driven by hindsight.

80. First, Eunsung touts Wunsch's benefits as supposed motivation for selecting its manifold, but then when carrying over the manifold to the Karasiuk-Palmer combination, Eunsung neglects to carry over the component allegedly providing that benefit. Eunsung alleges a POSITA would have been motivated because "Wunsch's manifold selector can be automatically controlled by the sequence-timer to allow automatic dispensing of different treatment fluids." Pet., 73. Wunsch makes clear that "[t]he quantity of solution dispensed is metered by a volumetric infusion pump." Ex. 1020, Abstract; *see also id.*, 7:57-65 ("[F]luid volume through the dispensing tube 18 is controlled by the volumetric infusion pump 20.").

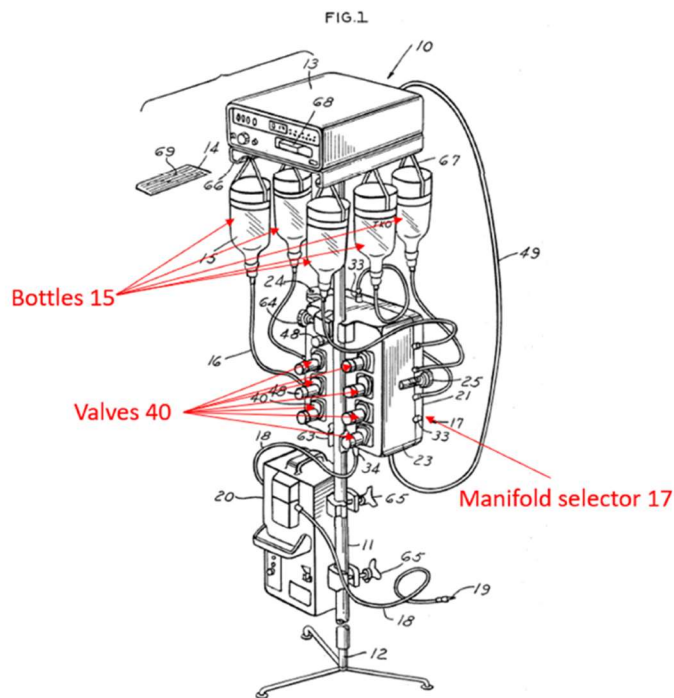
81. Yet, the Petition never incorporates Wunsch's infusion pump when combining Wunsch with Karasiuk and Palmer, and thus provides no means of regulating Wunsch's manifold selector through the sequencer-timer. *See* Pet., 74-

75. Instead, Eunsung attempts to incorporate only “Wunsch’s manifold selector and sequence timer.” Pet., 71. Without the infusion pump, the alleged automatic control has no feedback loop and, in my opinion, cannot function as intended.

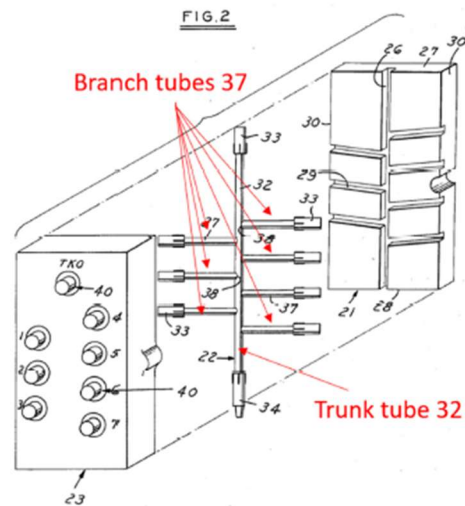
82. The component Wunsch discloses as responsible for the alleged benefits is the volumetric infusion pump. Ex. 1020, Abstract (Wunsch’s manifold selector can be automatically controlled by the sequence-timer to allow automatic dispensing of different treatment fluids.”); *see also id.*, 7:57-65 (“[F]luid volume through the dispensing tube 18 is controlled by the volumetric infusion pump 20.”).

83. In my opinion, Wunsch’s manifold selector and sequence timer (incorporated by Eunsung) without the volumetric infusion pump (not mentioned in the petition or Mr. Simon’s declaration even once) would result in “automatic control,” but would lack the necessary feedback loop, rendering the system inoperable.

84. Second, neither Eunsung nor Mr. Simon explains how Wunsch’s manifold selector and sequence timer could be applied to the existing combination of Karasiuk and Palmer. Eunsung attempts to extract Wunsch’s manifold selector 17—with its manifold 22, including trunk tube 32 and a plurality of branch tubes 37—and apply it to the combination of Karasiuk and Palmer, which is already overly complicated as I have discussed above.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

Pet., 69, 71.

85. In my opinion, combining Wunsch with the Karasiuk-Palmer system would only exacerbate its inoperability.

F. A POSITA Would Not Have Been Motivated to Modify Karasiuk

86. Eunsung alleges a POSITA would have been motivated to modify Karasiuk to use multiple types of skin treatments stored in separate containers during the same skin treatment. Pet., 9. Eunsung alleges the motivation would have come from two sources: “Based on [1] general knowledge and [2] Karasiuk’s disclosure,

a POSITA would have recognized the desirability of using multiple types of treatment solutions *during microdermabrasion*.” *Id.*

87. In my opinion, neither “general knowledge” nor “Karasiuk’s disclosure” provides a motivation to (1) use multiple types of treatment solutions *during microdermabrasion* or to (2) modify Karasiuk’s single-container system to add more containers and a “manifold.”

1. “General Knowledge” Was Not a Motivation

88. I was asked to opine on whether a person of ordinary skill in the art would have had the general knowledge necessary to modify Karasiuk.

89. In my opinion, the Petition and Mr. Simon’s declaration include no explanation of the “general knowledge” that would have supposedly motivated a POSITA to modify Karasiuk.

90. In my opinion, Mr. Simon’s understanding of “general knowledge” is fatally flawed for several reasons. Simon asserts that “multiple treatment solutions are desirable during microdermabrasion.” Ex. 1003, ¶84 (citing Burgess (Ex. 1013) and Lee (Ex. 1016)).

91. In my opinion, Simon’s cited evidence contradicts his assertion that treatment solutions are desirable *during microdermabrasion*. For example, the Burgess section cited by Simon states: “*When the treatment is completed*, residual crystals should be gently brushed off the skin,” then the skin can be “rinsed with

tepid water and a moisturizer with adequate sunscreen applied.” Ex. 1013, 86. In my view, this makes sense because, as Burgess explains, the traditional application of microdermabrasion involves the use of “fine, sharp crystals” to sandblast the skin. Ex. 1013, 84. In my view, it would be antithetical to apply moisturizer during a microdermabrasion procedure that is blasting the skin with fine, sharp crystals. Simon himself agrees, in describing Burgess, that moisturizer is applied “when microdermabrasion *is completed*.” Ex. 1003, ¶84. Thus, no treatment solution is applied *during* microdermabrasion, let alone multiple treatment solutions, as Simon alleges.

92. Simon cites to Lee as “general knowledge.” *Id.* In my opinion, Simon misapprehends the reference when he alleges “Lee discloses delivering vitamin C during microdermabrasion.” *Id.* (citing Ex. 1016, 1). In my view, Lee involves testing “the topical delivery of vitamin C” *after* laser treatment or microdermabrasion “using an *in vitro* model of nude mouse skin.” Ex. 1016, 1. In my view, the *in vitro* testing involves treating excised mouse skin with a laser or microdermabrasion, then mounting the skin fragment for 12 hours in a “Franz vertical diffusion assembly” filled with a vitamin C formulation to determine the “amount of vitamin C retained in the skin.” *Id.*, 2 (Materials and Methods). In my opinion, Lee does not provide any motivation to use multiple types of treatment solutions during microdermabrasion as Simon alleges.

93. Eunsung also relies on “general knowledge” to argue that “fluid delivery techniques required to use multiple containers with Karasiuk’s handpiece were well-known and part of a POSITA’s general knowledge.” In my opinion that Simon’s cited testimony in support of Eunsung’s assertions is conclusory. Ex. 1003, [85]-[89]. In my view, he fails to explain how incorporating structure from any of the disparate devices would, as he claims, “improve the flexibility and functionality offered by Karasiuk’s system.” *Id.*, [085].

94. In my opinion, the mere fact that multiple containers were used in some contexts would not have in any way suggested to a POSITA that using multiple containers would have improved Karasiuk’s single-container design.

2. “Karasiuk’s Disclosure” Was Not a Motivation

95. Eunsung points to “Karasiuk’s disclosure” as a motivation to modify Karasiuk. But as explained above, the argument is flawed. In my opinion, there is no disclosure in Karasiuk of using multiple types of treatment solutions from multiple containers in a single patient skin treatment procedure, and Eunsung does not argue otherwise. The only Karasiuk disclosure that Eunsung cites is: (1) the types of compounds that can be used in Karasiuk’s single reservoir 70 (e.g., “lotions/vitamins or other fluids”); and (2) Karasiuk’s boilerplate language that “various [undescribed] changes” may be made “without departing from the true spirit and scope of the invention.” Pet., 9-10 (quoting Ex. 1004, [0024], [0047],

[0061], [0070]). Simon cites and quotes these same passages from Karasiuk without further explanation. Ex. 1003, [78], [80].

96. Regarding the types of compounds disclosed in Karasiuk, they include, e.g., abrasive particles, bleaching formulations, acne treatment formulations, lines/wrinkle treatment formulations, hydrating formulations, and antioxidant formulations. Ex. 1004, [0061]. Karasiuk explains they can be “employed alone or in combination with other compounds” in a single reservoir 70. *Id.* In my opinion, a POSITA would have appreciated the simplicity of combining various constituents in a single step as part of a single mixture to achieve the benefits of each individual constituent. Eunsung points to no evidence a POSITA would have doubted the efficacy of applying the chosen constituents in a single step as part of a single mixture.

97. Turning to Karasiuk’s boilerplate, Eunsung fails to explain how its mention of “various changes” and “the true spirit and scope of the invention” (Ex. 1004, [0070]), would have motivated a POSITA to make any particular modification at all, let alone the detailed and specific modifications proposed by Eunsung of adding multiple types of treatment solutions in multiple containers, along with a manifold and associated connections and controls (valves) that allow selection of the treatment solutions. Such broad and vague language does not authorize Eunsung to

ex post read into Karasiuk concepts taken from the '052 patent to reconstruct the claimed inventions.

98. Thus, it is my opinion that “Karasiuk’s disclosure” contains no evidence of a motivation to modify Karasiuk’s system to include additional containers with treatment fluids and a manifold and valves to control the flow of treatment fluids.

3. Eunsung’s Reliance on Palmer Is Based Solely on Hindsight

99. Eunsung asserts that in view of “general knowledge” and “Karasiuk’s disclosure,” a POSITA “would have investigated other references such as Palmer to achieve benefits offered by multiple treatment solutions.” Pet., 10. But, as explained above, neither “general knowledge” nor “Karasiuk’s disclosure” could have plausibly motivated a POSITA to investigate other references as Eunsung claims. Eunsung’s entire foundation for a POSITA seeking out Palmer is erroneous.

100. It is no surprise then that the alleged “benefits” Eunsung has selected from Palmer are rooted in the needs of periodontal irrigation systems at the time, not any then-known skin treatment system. Eunsung’s attempt to shoehorn them into Karasiuk’s skin treatment system can only be explained with impermissible hindsight.

101. The first and second alleged benefits are “allow[ing] easy selection among multiple treatment solutions” and “enabl[ing] sequential delivery of different

treatment solutions.” Pet., 10-11. However, both benefits are premised on Palmer’s described need for multiple irrigating solutions delivered sequentially in a periodontal procedure—i.e., hydrogen peroxide for “removal of loose organic debris,” zinc chloride for “reduc[ing] inflammation,” sodium fluoride for “desensitization of tooth structure,” and stannous fluoride and chlorhexidine digluconate for “reduction of bacterial concentration.” Ex. 1005, 1:33-43; *id.*, 5:52-64. Palmer’s motivation was, as Eunsung agrees, the drawback in “conventional irrigation arrangements” that did not provide “the opportunity of easy selection among several irrigant solutions.” Petition, 10-11 (quoting Ex. 1005, 1:30-53).

102. Palmer’s additional disclosure further informs a POSITA the sequential delivery was actually unique to periodontal irrigation systems, which involved color coding the solutions and use of “flavor coordinated” solutions. Ex. 1005, 3:42-48. Using “substantially the same predetermined flavor” allows a patient to be “treated with two or more solutions during the procedure, *one after the other*, without being subjected to the discomfort which would normally occur when a person tastes two or more *diverse flavors, one immediately after the other.*” Ex. 1005, 6:42-51. Eunsung erroneously cites this passage in alleging POSITA would have applied Palmer’s teachings to Karasiuk’s skin treatment system, but the sequential delivery is clearly meant for periodontal irrigation systems. Pet., 11.

103. Dental clinicians would have recognized the lack of easy selection among irrigant solutions to be a problem for dental-irrigation devices because delivering multiple dental-irrigation solutions together in a single step would necessarily dilute and destroy the efficacy of many such solutions. By contrast, Eunsung does not identify any such drawback with Karasiuk's skin treatment system; rather, a POSITA would have expected Karasiuk's delivery of a mixture of treatment fluids in a single step to achieve the efficacy of each of individual fluids. Therefore, Eunsung has not shown that clinicians would have recognized any problem with Karasiuk's single-container design in need of a solution. This is because the automated control and use of multiple liquid treatment solutions for a single patient skin treatment procedure had not been invented prior to the '052 Patent family.

Eunsung also relies on the following assertion of Palmer in the first benefit:

If circumstances require the use of a different treatment solution, either with the same or a subsequent patient, the solution remaining in the tank is usually discarded and the tank must be cleaned and refilled with the new solution. This procedure is time-consuming and costly, not to mention messy.

Ex. 1005, 1:47-53 (cited by Pet., 11). Palmer's opinion that cleaning and refilling a dental-irrigation tank is a time-consuming, costly, and messy procedure is irrelevant to Karasiuk's skin treatment procedure. Neither Eunsung nor Simon

asserts a POSITA would have found cleaning or refilling Karasiuk's reservoir to be sufficiently time-consuming, costly, and messy to justify adding more containers and a complicated fluid-selection control system and plumbing structure to Karasiuk's device. In fact, in my opinion, a POSITA would have expected the operation of Karasiuk's single-container device to be *less* time-consuming, costly, and messy than Eunsung's proposed multi-container device.

104. The third alleged benefit is “minimiz[ing] refilling downtime because when a particular container runs out mid-operation, the combined system can quickly switch to a second container to keep the supply flowing.” Pet., 11. However, Eunsung presents no evidence a POSITA would have considered Karasiuk's reservoir to be too small to contain sufficient treatment fluid for its purpose. And if the size of Karasiuk's reservoir were a concern, Eunsung presents no evidence a POSITA would have been motivated to add complicated valves and tubing simply to allow a clinician to switch to an extra container of the same treatment fluid. Indeed, in my view, a POSITA would have simply increased the size of Karasiuk's reservoir so it could contain the amount of treatment fluid required for most procedures. Because nothing in Karasiuk restricts the size of the reservoir, a POSITA would have understood Karasiuk as teaching or suggesting the use of a reservoir adequately sized for Karasiuk's purpose. Moreover, Eunsung presents no evidence clinicians could not quickly refill the reservoir for abnormal procedures

requiring more treatment fluid than usual, or that the possibility of such abnormal procedures would drive a POSITA to add structure unnecessary for most procedures.

105. The fourth alleged benefit is “Palmer’s modular design to provide added flexibility, organization, and portability.” Pet., 11. But this supposed benefit is irrelevant to Eunsung’s proposed change from Karasiuk’s single-container design to a multi-container automated liquid flow control design. Rather, as Eunsung recognizes, it relates to the desirability of container placement in a variety of *locations*, such as on a countertop, on a mobile cart, in a cabinet, or underneath a counter. Pet., 11-12.

106. In sum, it is my opinion that Eunsung’s citation to Palmer’s benefits for periodontal irrigation is premised entirely on a hindsight reconstruction of the claimed invention. Eunsung presents no evidence a POSITA would have appreciated any of these benefits in the field of skin treatment before the priority date of the ’052 patent. While those in the field now understand the benefits of, e.g., sequential delivery in view of the teachings of the ’052 patent and the success of HydraFacial’s commercial embodiments of the ’052 patent, it would be legally improper to assume, without evidence, that a POSITA would have appreciated those benefits at the time of the invention.

VI. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

107. I have been asked to evaluate whether the HydraFacial Syndeo, HydraFacial Elite, HydraFacial Allegro, and HydraFacial Tower² (collectively, “HydraFacial Systems”) practice Claim 1 of the ’052 Patent. In addition, I have been asked to provide expert analysis on whether the HydraFacial Systems embody Claim 1 of the ’052 Patent and are coextensive with it to establish a presumed nexus.

108. I have analyzed the relevant aspects of each of the HydraFacial Systems in light of Claim 1 of the ’052 Patent, and, as set forth in detail below, it is my opinion that each of the HydraFacial Syndeo, HydraFacial Elite, HydraFacial Allegro, and HydraFacial Tower practices Claim 1 of the ’052 Patent, and are coextensive with this claim.

A. The HydraFacial Systems Meet Every Limitation of Claim 1 of the ’052 Patent

109. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 1 of the ’052 Patent.

110. Claim 1 recites as follows:

1. A system for performing a skin treatment procedure, the system comprising:

²The HydraFacial “Tower” system includes multiple models, including the HydraFacial Tower 120V, HydraFacial MD Tower 120V, HydraFacial Tower 240V, and HydraFacial MD Tower 240V (collectively referred to herein as the “HydraFacial Tower”).

a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

a vacuum source;

a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

I address each limitation of this claim below.

1. “A system for performing a skin treatment procedure, the system comprising:”

111. In my opinion, each of the Syndeo, Elite, Allegro, and Tower is “a system for performing a skin treatment procedure.”

112. The Syndeo IFU, for example, describes the Syndeo as a “System [that] is intended to abrade (exfoliate) the upper layers of the Skin.” Ex. 2030 at 4 (Syndeo

IFU). The Syndeo IFU also describes a step of the treatment by stating “Place tip against skin to occlude and dab skin solution onto skin.” *Id.* at 19.

113. I also confirmed the Syndeo is a system for performing a skin treatment procedure” after examining a Syndeo device. Below is a photo³ of the Syndeo device I inspected:



(Syndeo).

114. The Elite IFU describes the Elite as a “System [that] is intended to abrade (exfoliate) the upper layers of the skin.” Ex. 2031 at 4 (Elite User Guide).

³ All photos of the Syndeo, Allegro, and Elite are photos I personally took during inspections of each device. All photos of the Tower were provided by counsel and obtained at my direction.

115. I also confirmed the Elite is “a system for performing a skin treatment procedure.” after examination of an Elite device. Below is a photo of the Elite device I inspected:



(Elite).

116. The Allegro IFU describes a system that is “intended use is to abrade the upper layers of the skin by operator controlled motion, in order to smooth the skin surface and improve the appearance of skin, i.e. fine lines and wrinkles.” Ex. 2032 at 4 (Allegro IFU).

117. I also confirmed the Allegro is “a system for performing a skin treatment procedure.” after examination of an Allegro device. Below is a photo of the Allegro device I inspected:



(Allegro).

118. The Tower Owner’s Manual describes the Tower as a “revolutionary breakthrough in aesthetic technology” that performs a process that “removes dead skin cells and impurities while simultaneously infusing the new skin with cleansing, hydrating and moisturizing serums [and] antioxidants.” EX 2033 at 3.

119. I also reviewed photographs and videos of a Tower device to confirm my understanding that the Tower is “a system for performing a skin treatment procedure.” An image from one of the videos I reviewed is shown below:



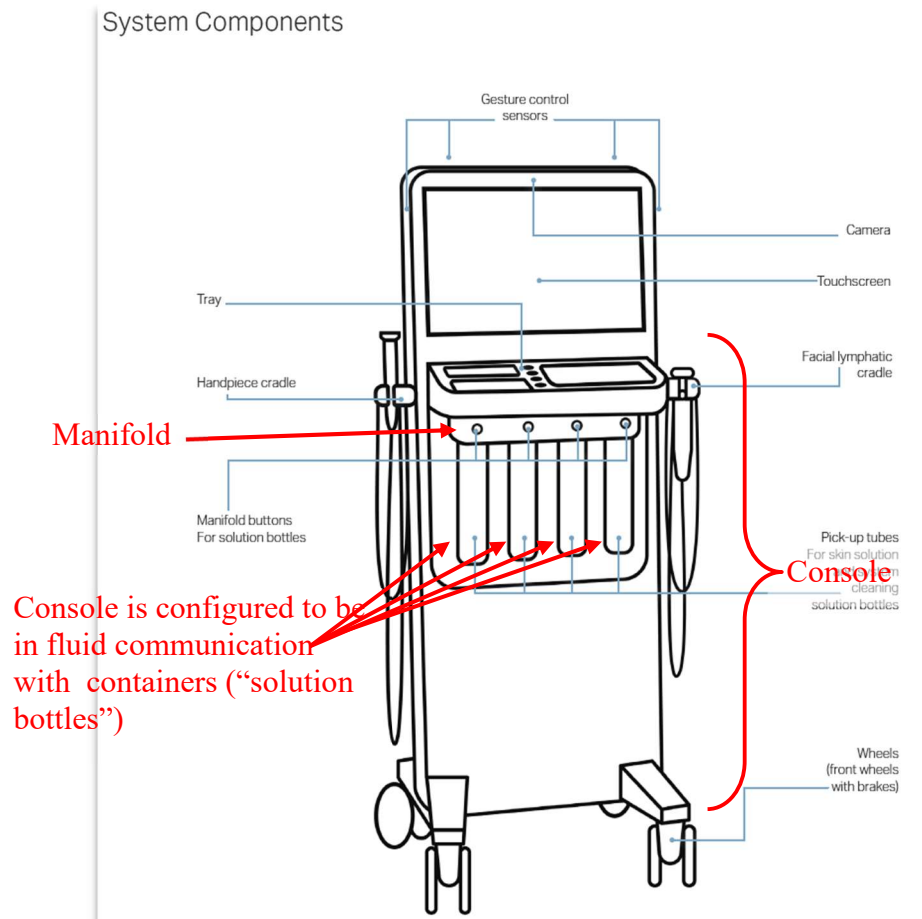
(Tower).

120. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

2. **“console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;”**

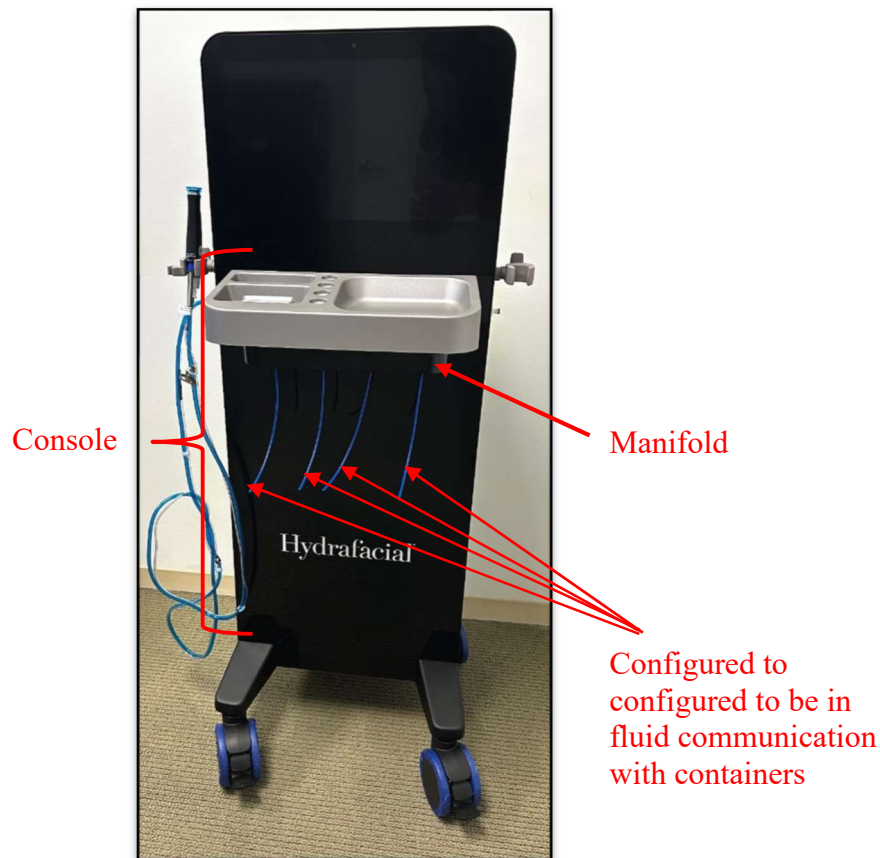
121. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has “a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid.”

122. I have reviewed the Syndeo IFU, which depicts the Syndeo, including a console:

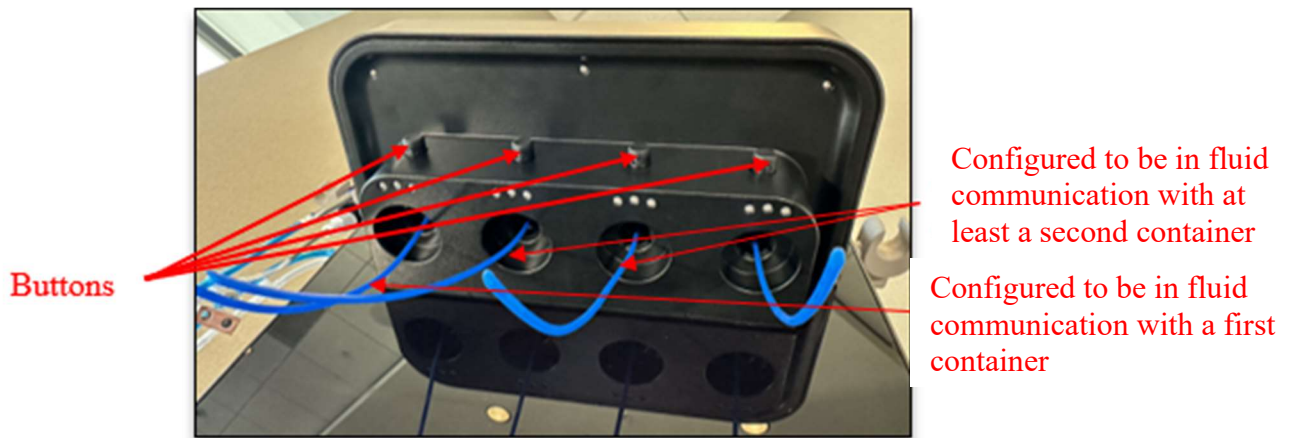


Ex. 2030 at 10 (Syndeo IFU). As can be seen in the image above, the manifold of the console is configured to be in fluid communication with a first container and at least one additional container.

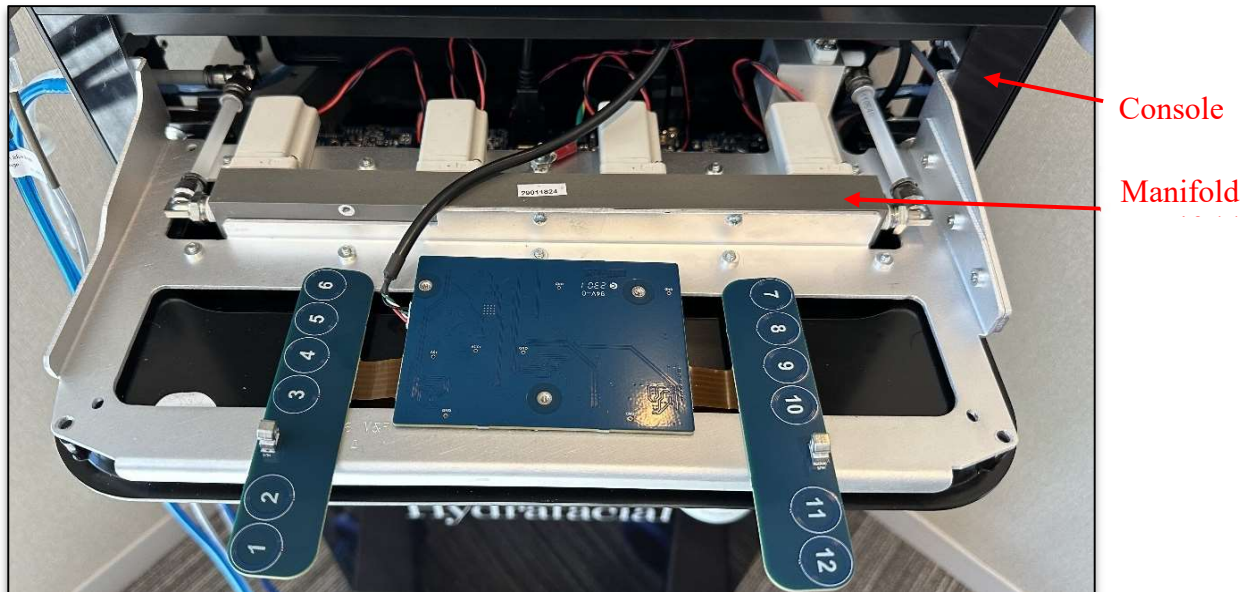
123. My inspection of the Syndeo confirmed the Syndeo has a console configured to be in fluid communication with a first container and at least one additional container. Below is an image of the Syndeo device I inspected, showing the Syndeo console configured to be in fluid communication with a first container and at least one additional container:



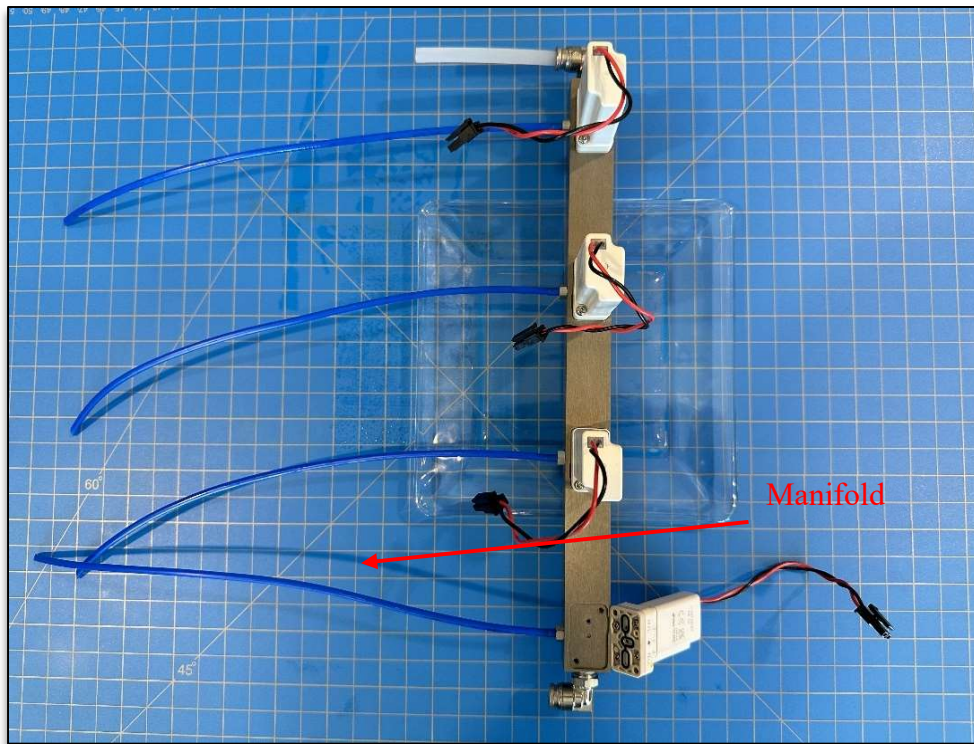
(Syndeo). The console can be in fluid communication with the containers when a user depresses buttons corresponding to respective containers.



(Syndeo). The manifold is in the console.

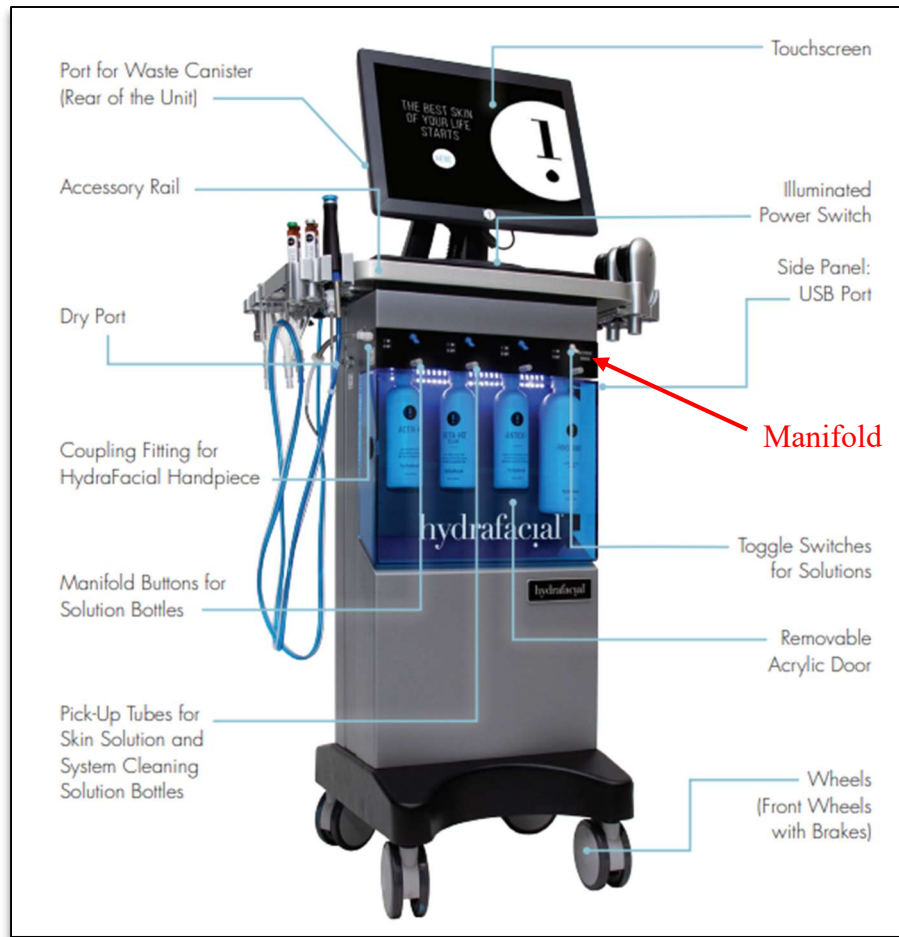


(Syndeo). The photo below shows the manifold removed from the console of the HydraFacial Syndeo system:



(Syndeo).

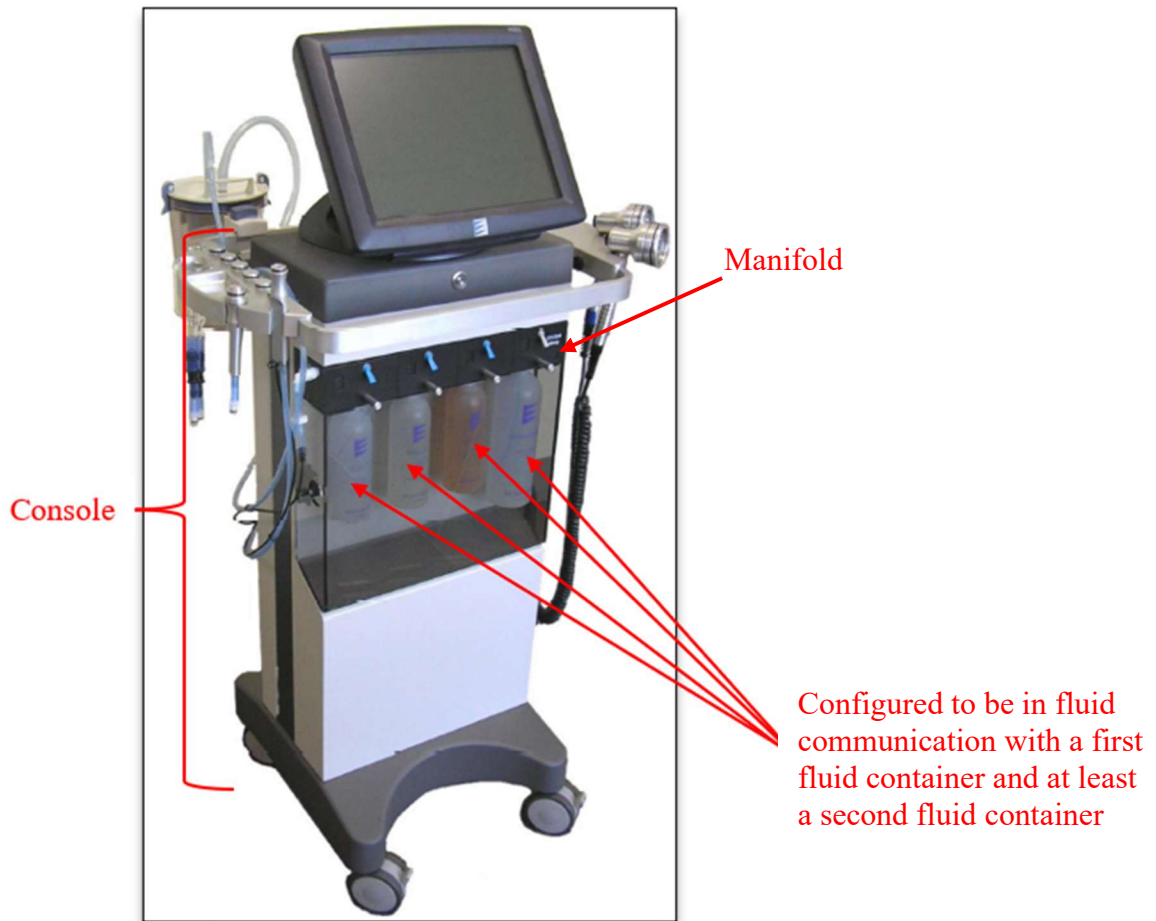
124. I have also reviewed the Elite IFU, Allegro IFU, and Tower Owner's Manual, each of which depicts their respective device as a system and console configured to receive a first container and additional containers. Annotated images from the Elite IFU, Allegro IFU, and Tower Owner's Manual are included below:



Ex. 2031 at 10 (Elite User Guide).

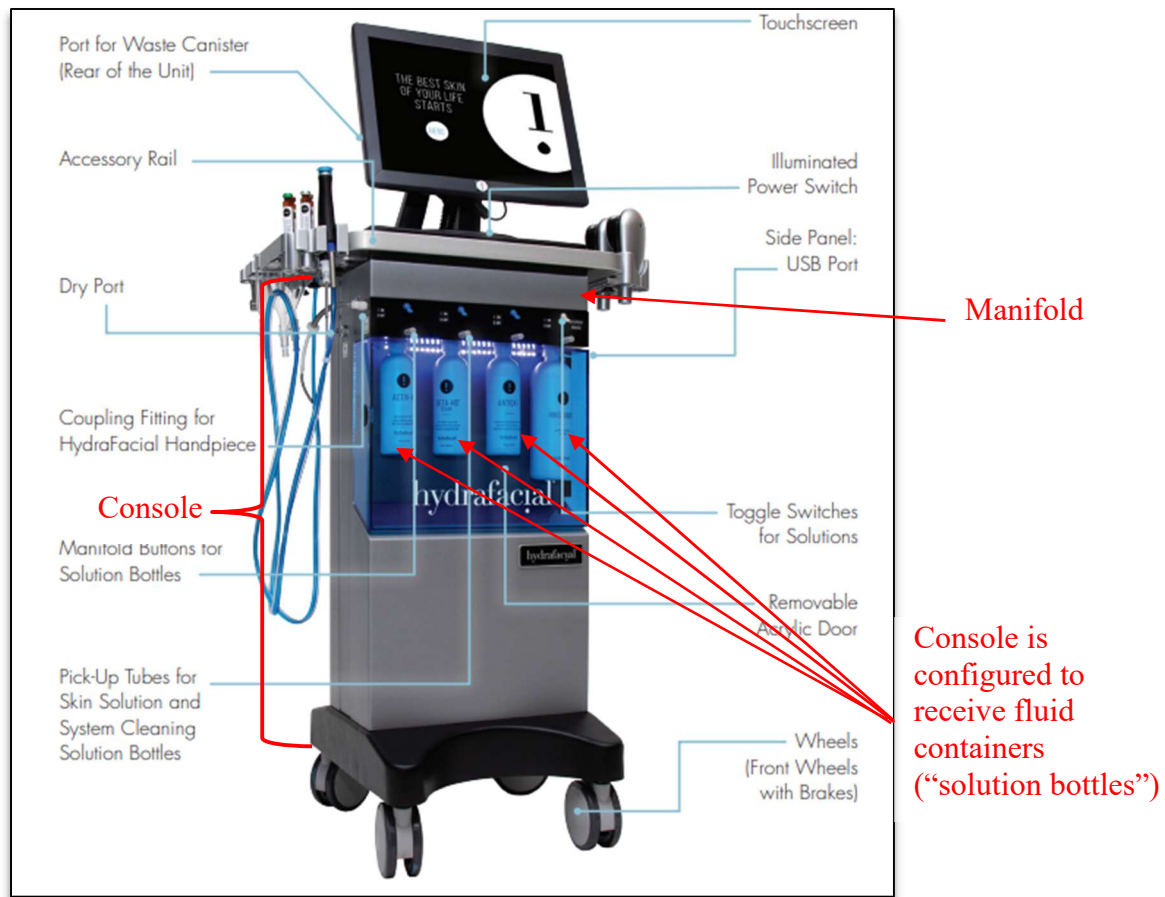


Ex. 2032 at 8 (Allegro IFU).



Ex. 2033 at 1 (Tower Owner's Manual).

125. My inspections of the Elite and Allegro confirmed that each has a console configured to receive a first container and at least one additional container. Below are images of the Elite and Allegro devices I inspected, showing the Elite and Allegro consoles, each configured to receive a first container and at least one additional container.

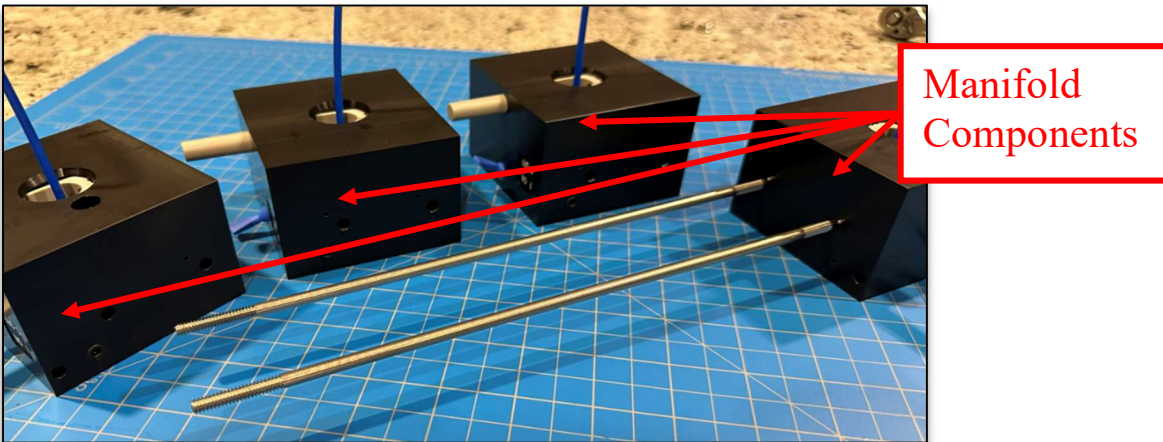


(Elite).



(Allegro).

126. The manifold comprises individual components that are connected together through two bolts running through the manifold.



127. Similarly, the Elite and Allegro technical documents each also describe connecting the fluid containers (including the first and second fluid containers) to the console such that the manifold is configured to receive fluid from the containers (including the first and second fluid containers).

Skin Solution Bottles (Sold separately)

1. Open the front door. Remove the cap of the skin solution bottle and use the puncture tool to pierce the seal inside the bottle.
2. Press and hold each manifold button as you insert each bottle into the manifold, and then release the button.

Note: The Device Rinse™ System Cleaning Solution should be installed in the manifold with the gray toggle switch labeled "SYSTEM RINSE".



Ex. 2031 at 13 (Elite User Guide).

Skin Solution Bottles

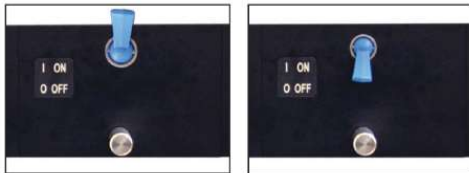
1. Open the front door. Remove the cap of the skin solution bottle and use the puncture tool to pierce the seal inside the bottle.
2. Press and hold each manifold button as you insert each bottle into the manifold, and then release the button.

Note: The Rinseaway™ System Cleaning Solution should be installed in the manifold with the gray toggle switch labeled "SYSTEM RINSE".



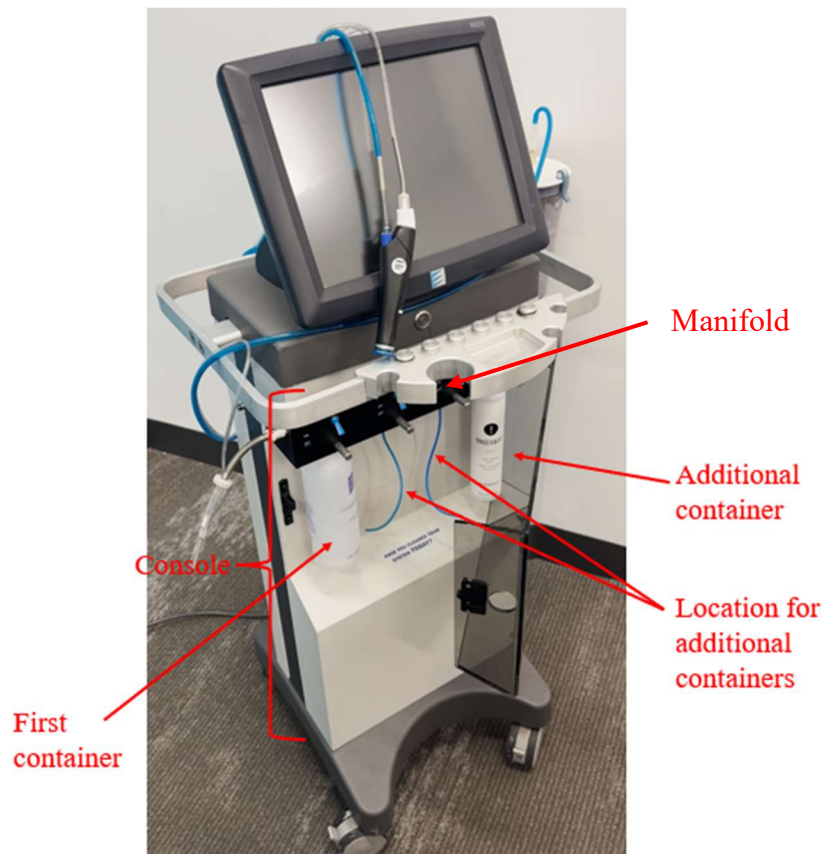
3. The toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle.

Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off while performing procedures.



Ex. 2032 at 11 (Allegro IFU). The toggle switches on the manifold are used to draw fluid from the fluid containers, including the first and second fluid containers, thereby putting the manifold in fluid communication with the first and second fluid containers.

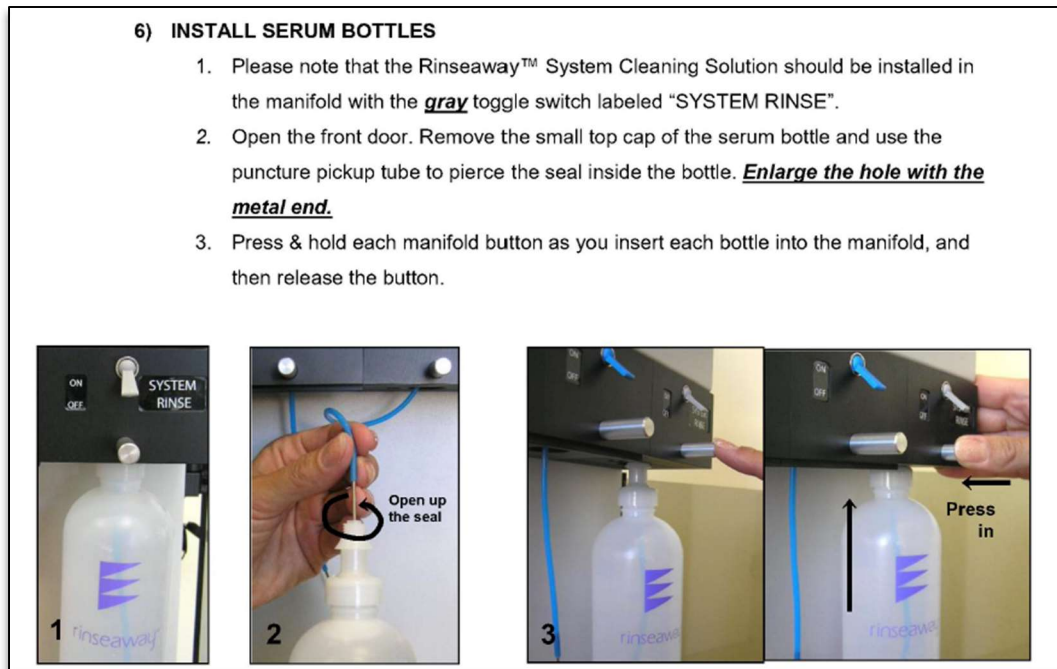
128. My review of videos and images of the Tower confirmed it has a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. Below is an image of a Tower device, showing that the Tower is configured to receive a first container and at least one additional container:



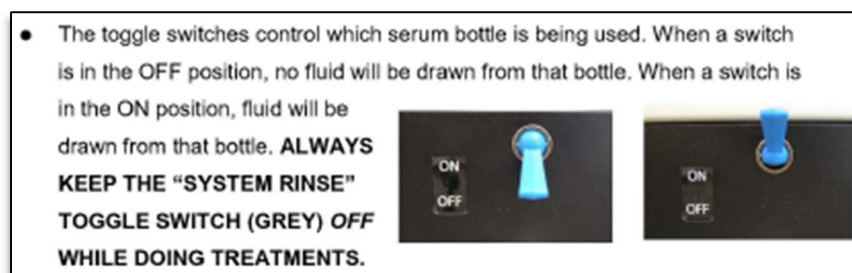
(Tower).

129. As can be seen in the images above, the manifolds for the Syndeo, Elite, Allegro, and Tower are each configured to be in fluid communication a first fluid container, as well as at least a second fluid container.

130. Similarly, the Owner's Manual for the Tower provides guidance for how to "install" (connect) the serum bottles to the manifold, which is part of the console.



Ex. 2033 at 13 (Tower Owner's Manual). As shown above, tubing to receive fluid from containers enters the container, allowing the manifold to receive fluid from the containers. Toggle switches on the block determine which container the manifold will receive fluid from.



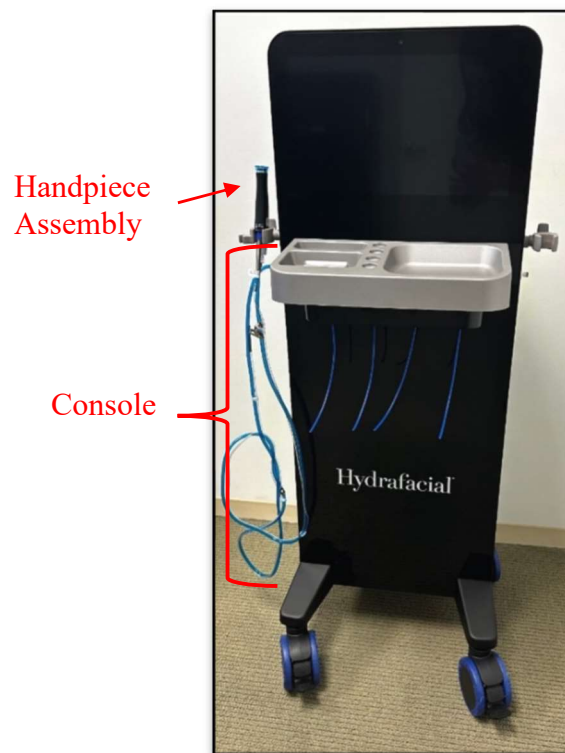
Ex. 2033 at 13 (Tower Owner's Manual).

131. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

3. “a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;”

132. In my opinion, each of the Syndeo, Elite, Allegro, and Tower includes a “a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject .”

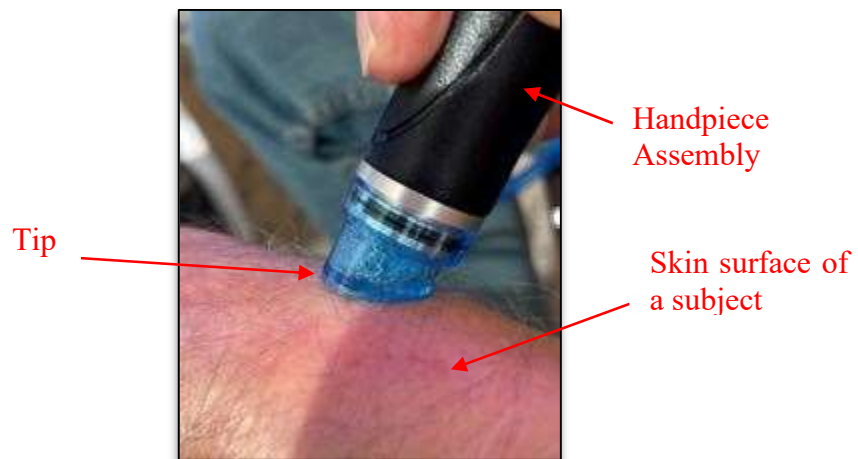
133. During my inspection of each of the Syndeo, Elite, Allegro, and Tower, I observed that each included a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject as shown in the images below.



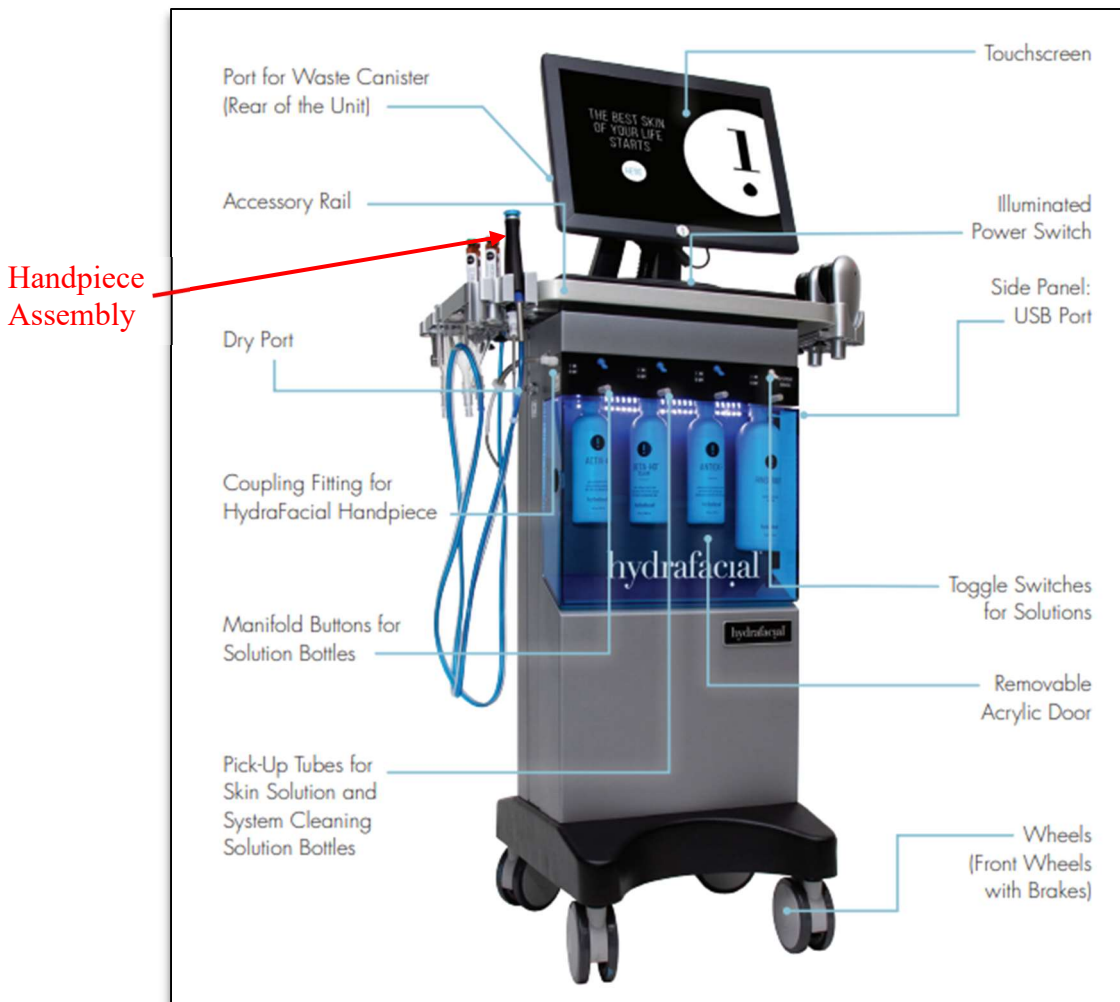
(Syndeo)



(Syndeo). The photo below shows the handpiece assembly contacting the skin surface of a subject during a treatment procedure.



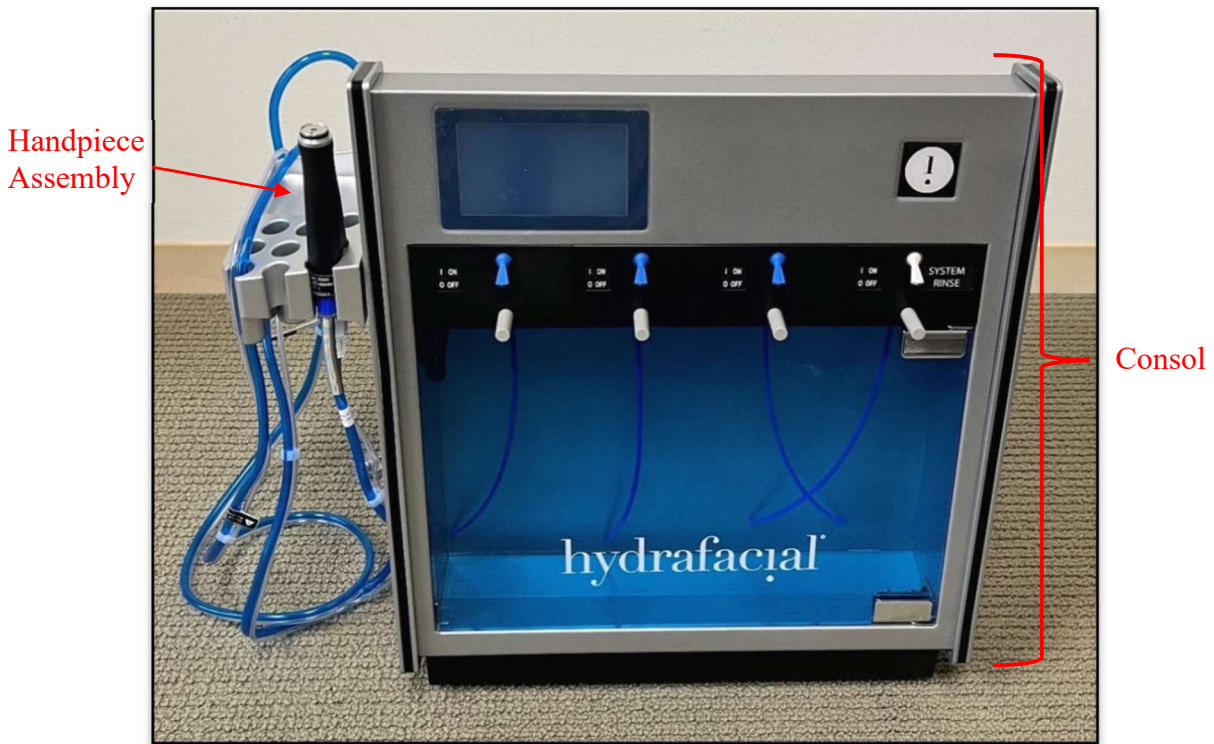
(Syndeo)



(Elite).



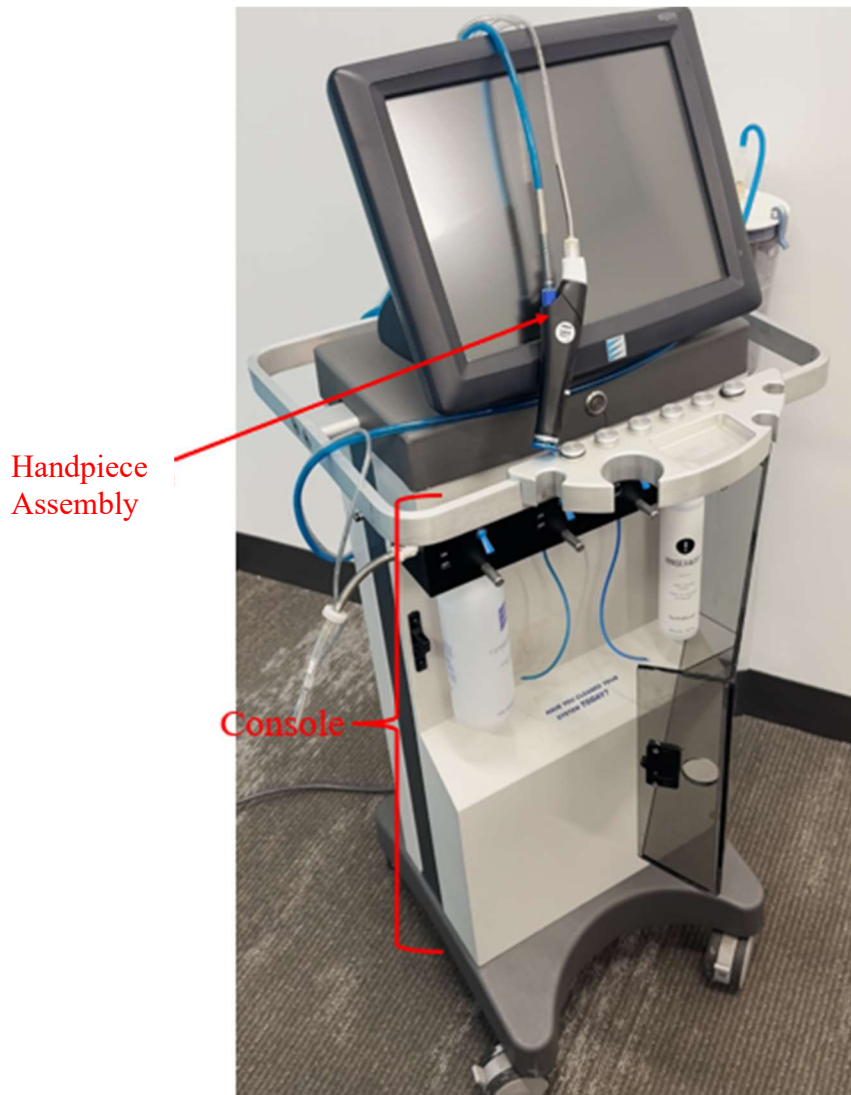
(Elite).



(Allegro).

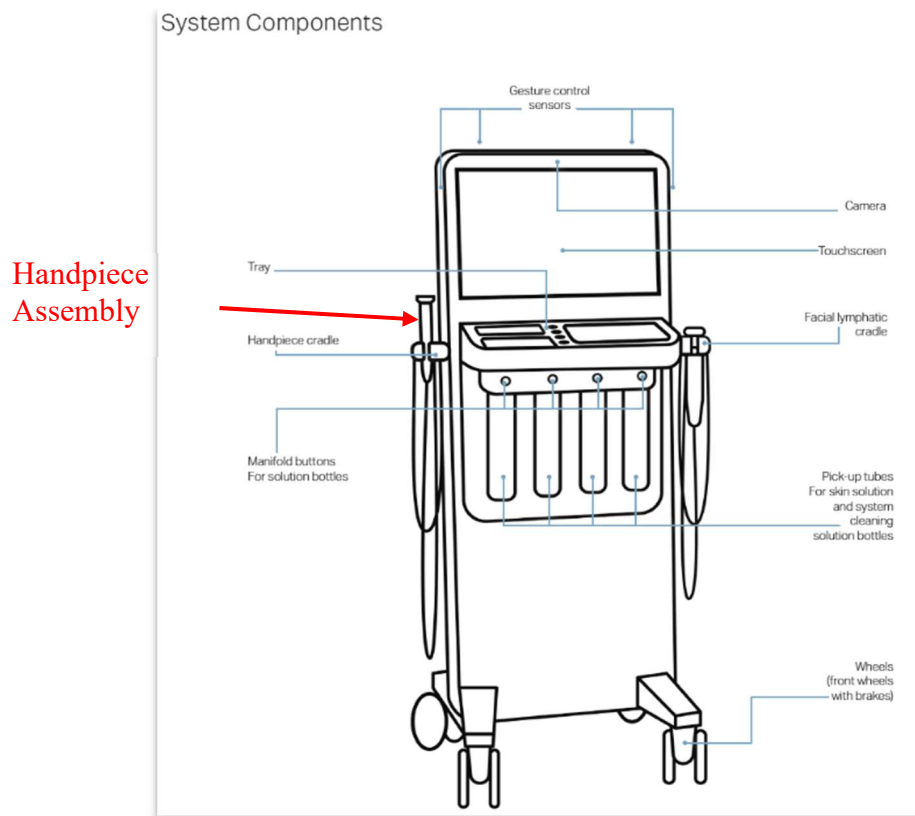


(Allegro).



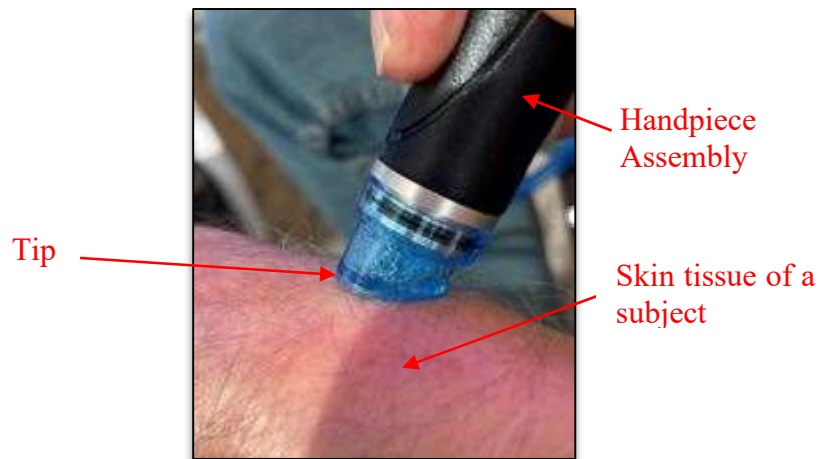
(Tower).

134. In addition, the Syndeo User Manual, the Elite IFU, Allegro IFU, and Tower Owner's Manual confirm that each of the four devices includes a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject. For example, an image from the Syndeo User Manual is depicted below:

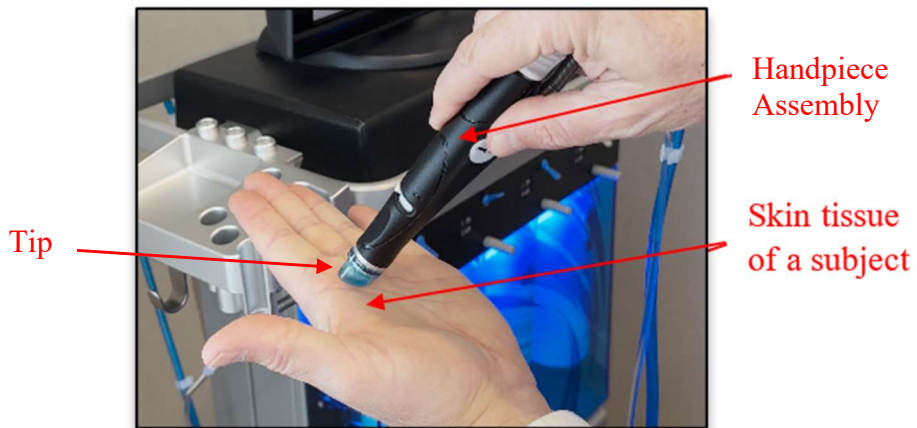


Ex. 2030 at 10 (Syndeo IFU). The Syndeo IFU explains that the tip of the handpiece assembly is used to contact the skin surface of a subject, instructing the user to “[p]lace a tip on the handpiece,” and “[p]lace tip against skin to occlude and dab skin solution onto skin.” *Id.* at 19.

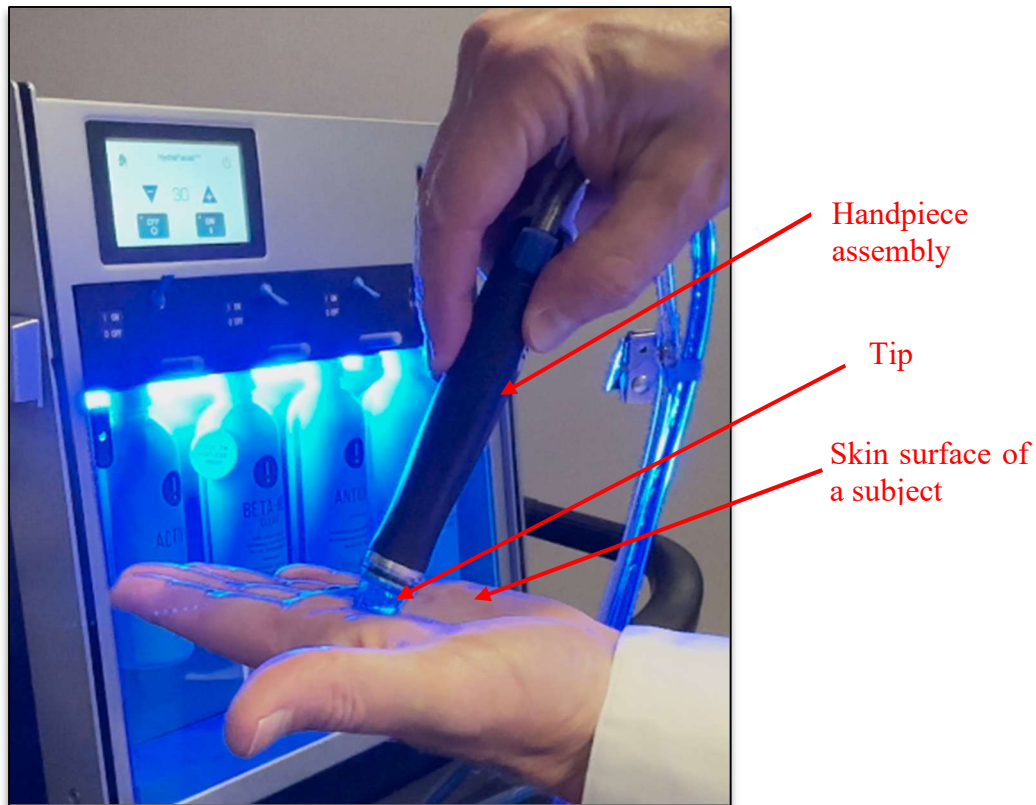
135. For all four devices, in operation, the handpiece assembly is intended to be held in the hand and the tip of the handpiece assembly placed in contact with the skin, as confirmed by videos of the devices in operation. A screenshot from the video shows the handpiece assembly in contact with skin surface. From this, I concluded the tip of the handpiece assembly is configured to contact skin surface of a subject, as shown below.



(Syndeo).



(Elite).



(Allegro).

136. Given the similarity between the Tower handpiece assembly and Allegro and Elite handpiece assemblies, I have concluded that the tip of the Tower handpiece assembly would contact the skin surface of a subject, similar to the images above.

137. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

4. **“a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a**

distal end of the supply conduit is configured to couple to the handpiece assembly;”

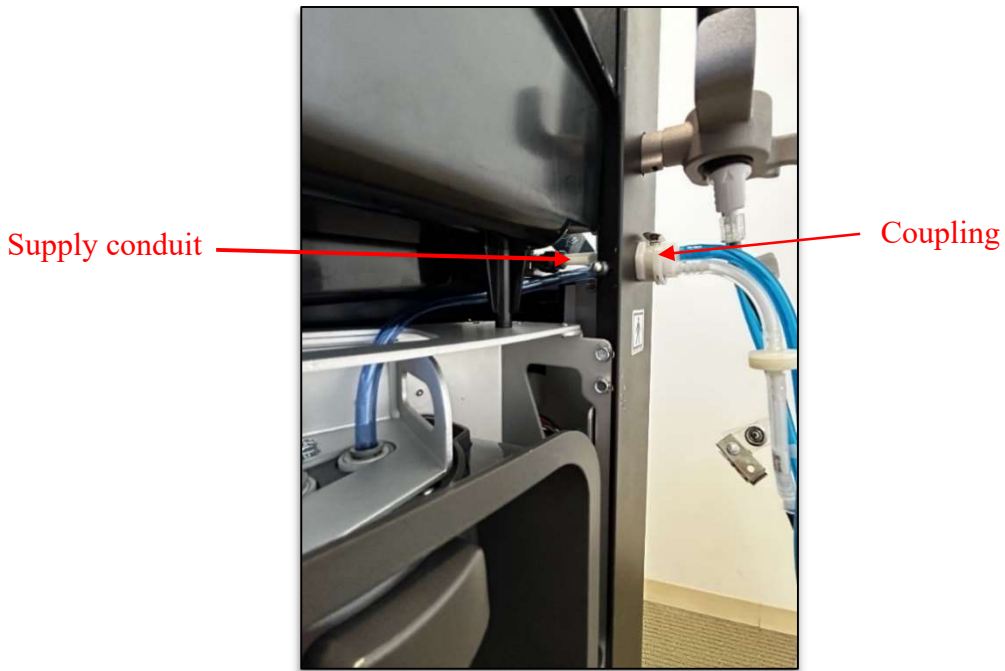
138. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has “a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly.”

139. As part of my inspection of the Syndeo, I opened the console. In the console, I observed the supply conduit extending from the manifold. An annotated image of the supply conduit in the console of the Syndeo system is included below.

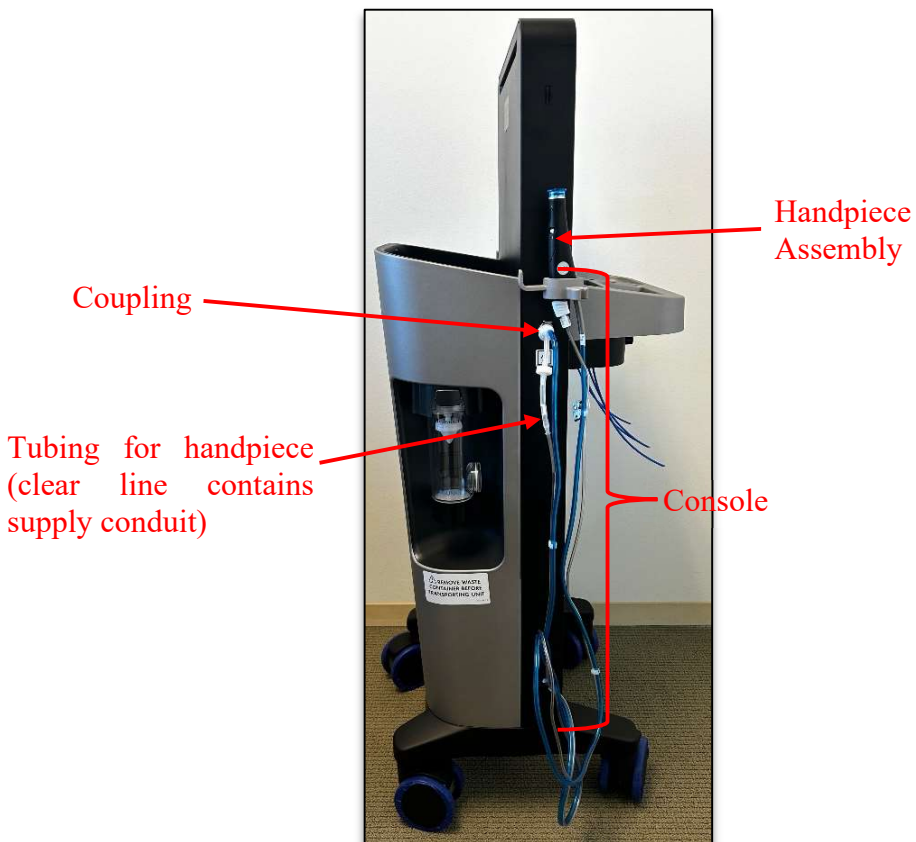


(Syndeo)

140. During my inspection, I further confirmed the supply conduit places the manifold of the console in fluid communication with the handpiece assembly. The annotated photographs below show the supply conduit placing the manifold of the console in fluid communication with the handpiece assembly.

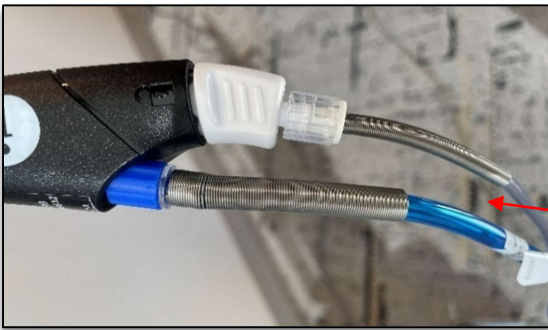


(Syndeo)



(Syndeo)

141. In addition, during my inspection of the Syndeo device, I confirmed the distal end of the supply conduit of the Syndeo is configured to couple to the handpiece assembly. Annotated photographs below show the distal end of the supply conduit coupled to the handpiece assembly.



Supply conduit

(Syndeo)



Supply conduit

Handpiece
Assembly

(Syndeo)

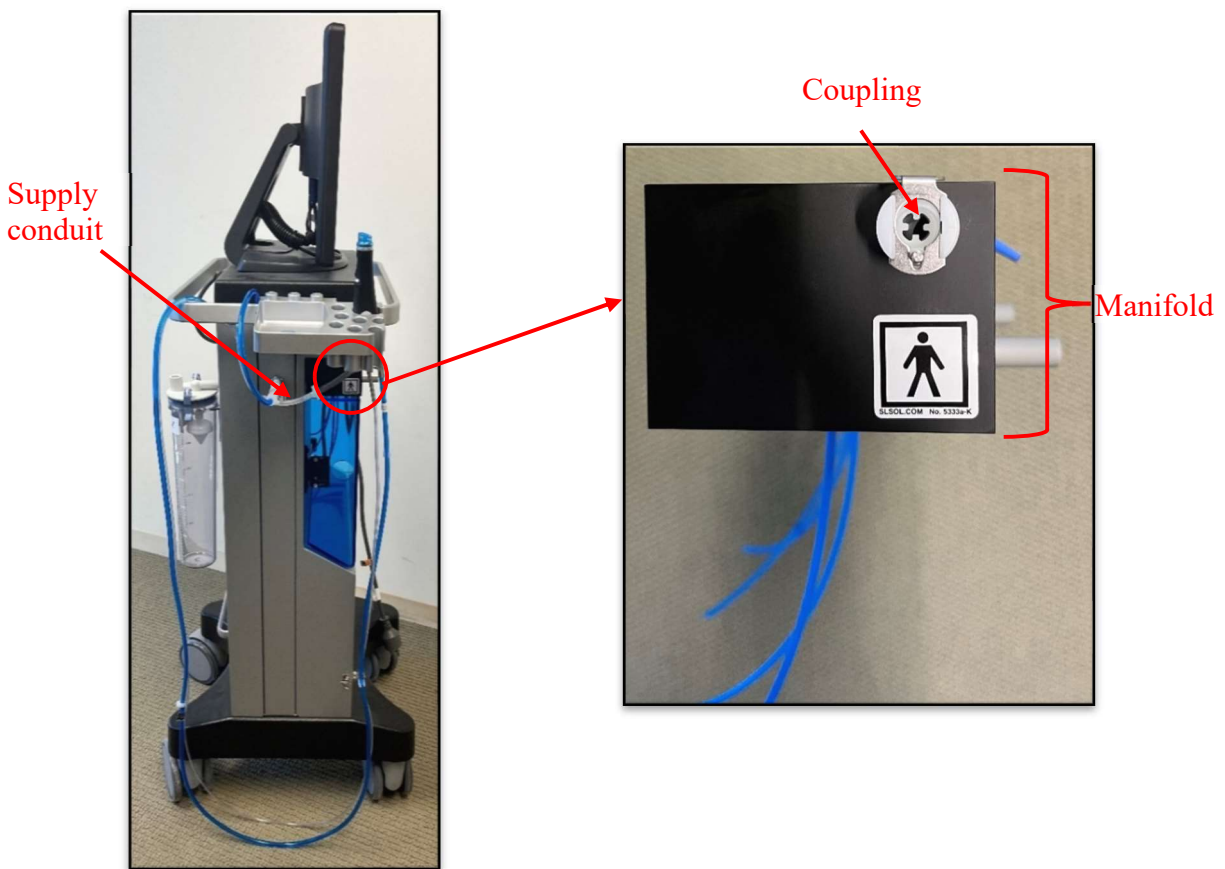


Handpiece
Assembly

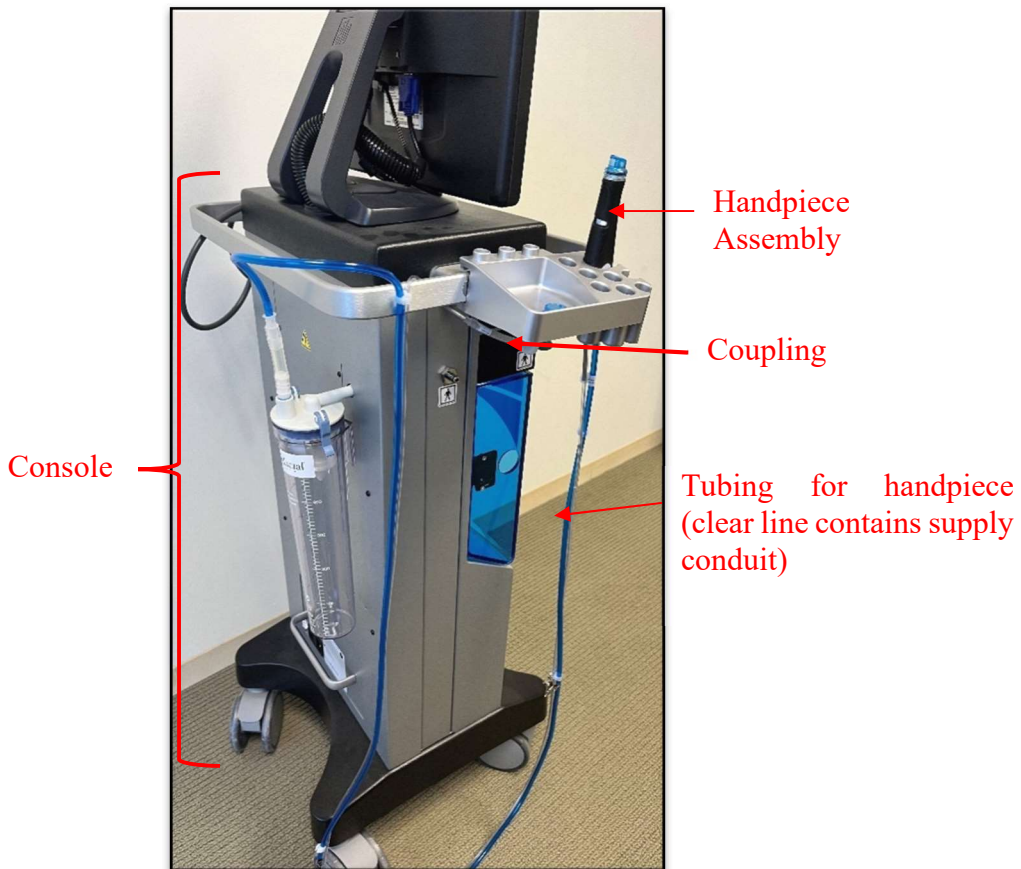
Supply
conduit

(Syndeo)

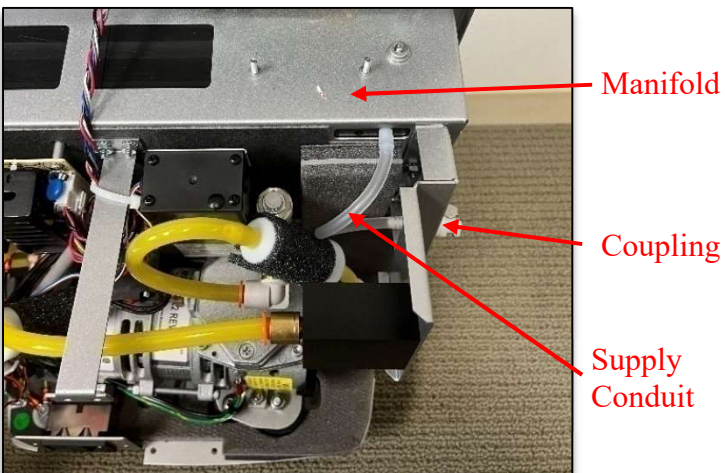
142. As part of my inspection of the Elite and Allegro, I opened their respective consoles. In each console, I observed a supply conduit extending from the manifold—I further observed that the distal end of the supply conduit is configured to couple to the handpiece assembly. Annotated images of the supply conduit, manifold, and coupling for the Elite and Allegro are included below.



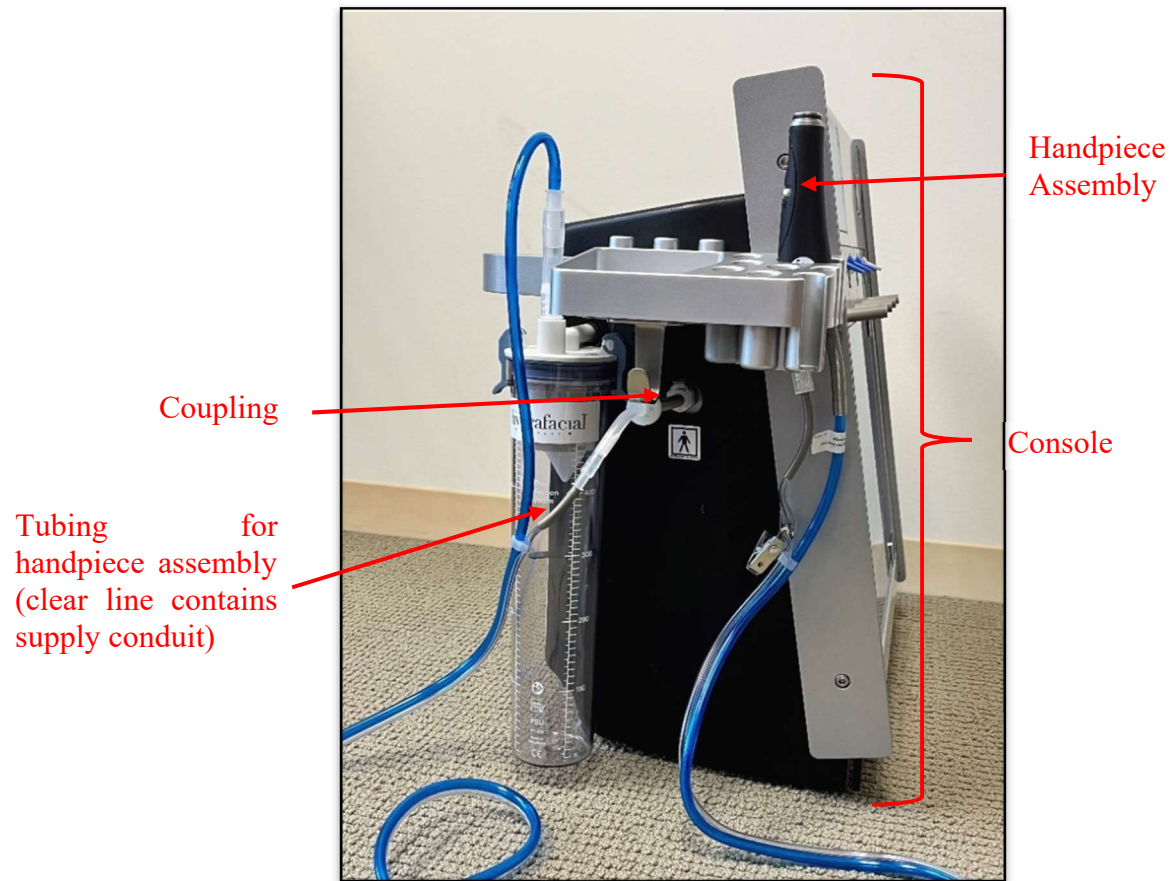
(Elite)



(Elite)



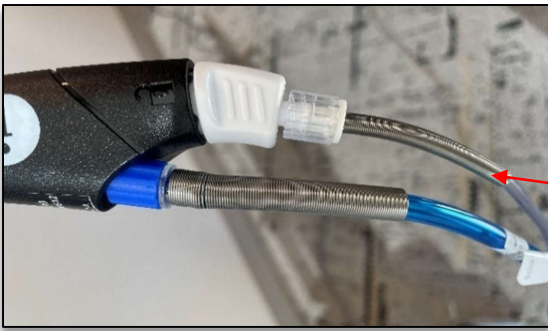
(Allegro)



(Allegro)

143. The annotated technical drawing below shows the manifold of the Elite having a coupling to which tubing to the handpiece assembly (including a portion of the supply conduit) connects.

144. Annotated photos of the Syndeo supply conduit being coupled to the handpiece assembly are below.



Supply conduit

(Syndeo)



Supply conduit

Handpiece
Assembly

(Syndeo)



Handpiece
Assembly

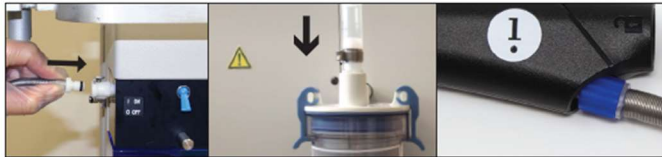
Supply
conduit

(Syndeo)

145. The Elite IFU confirms my understanding and describes connecting a “Supply Line” between the handpiece assembly and the console, where the “Supply Line” serves as the supply conduit through which the manifold is in fluid communication with the handpiece assembly.

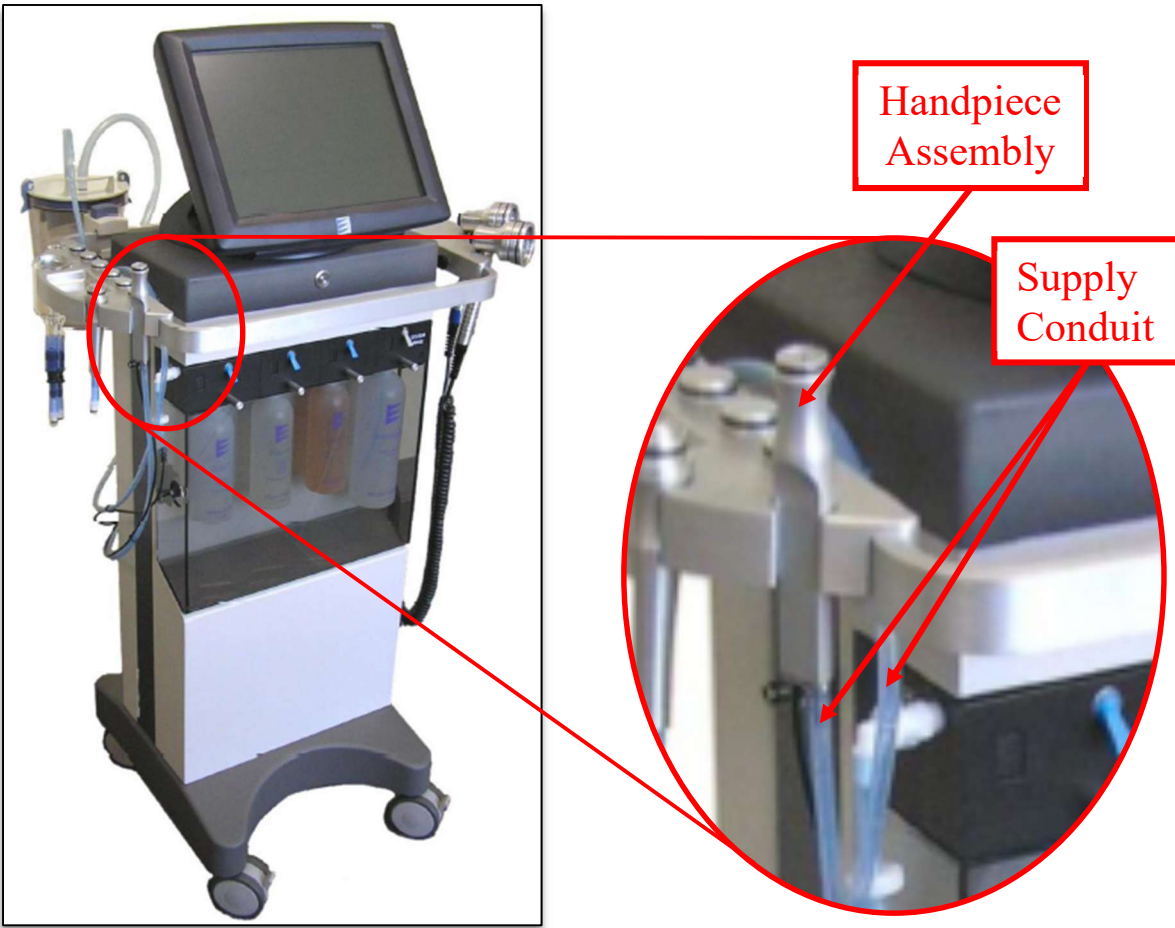
HydraFacial Handpiece

1. Connect the blue twist lock (Return Line) to the blue connector on the bottom of the handpiece and secure by twisting thumb tight. Do not overtighten.
2. Connect the clear twist lock (Supply Line) to the cartridge and secure it by twisting the lock only thumb tight. To prevent the lock from breaking, do not overtighten the twist lock.
3. Plug the small tube attached to the handpiece into coupling fitting in the System.
4. Connect the large tube attached to the handpiece into the waste canister.



Ex. 2031 at 12 (Elite IFU).

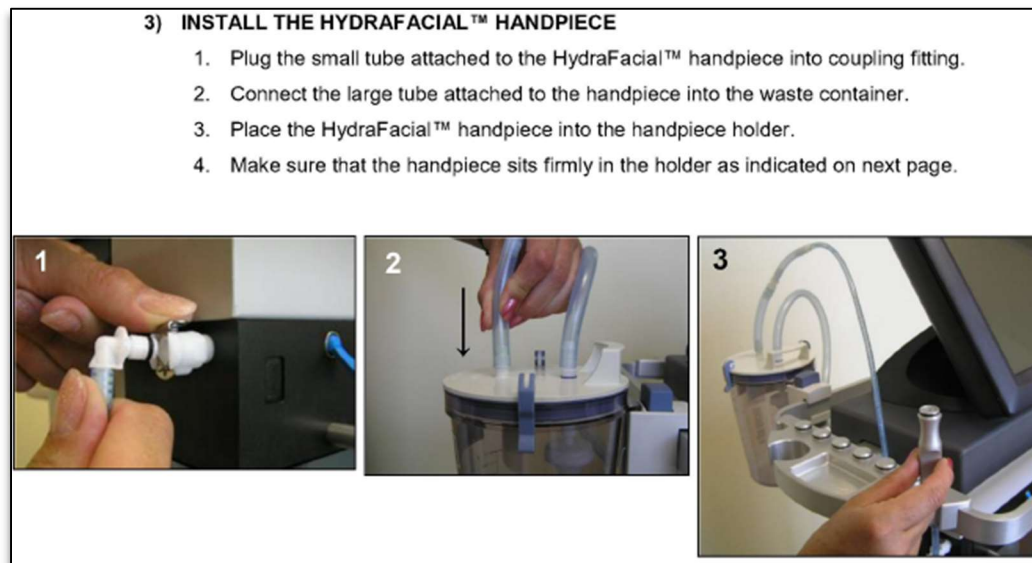
146. My review of videos and images of the Tower confirmed it has “a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly.”



Ex. 2033 at 1 (Tower Owner's manual).

147. The Tower Owner's Manual confirms my understanding and describes connecting a "small tube" between the handpiece assembly and the console, where the "small tube" serves as the supply conduit through which the manifold is in fluid

communication with the handpiece assembly.



Ex. 2033 at 10 (Tower Owner's Manual). The supply conduit extends from the manifold in the console through tubing to the handpiece assembly.

148. Given the similarities between the Syndeo handpiece assembly and the Elite, Allegro, and Tower handpiece assemblies, I have concluded the distal end of a supply conduit would be coupled to the handpiece assembly for each of the Elite, Allegro, and Tower similar to the images above.

149. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

5. “wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and”

150. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has a manifold “configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.”

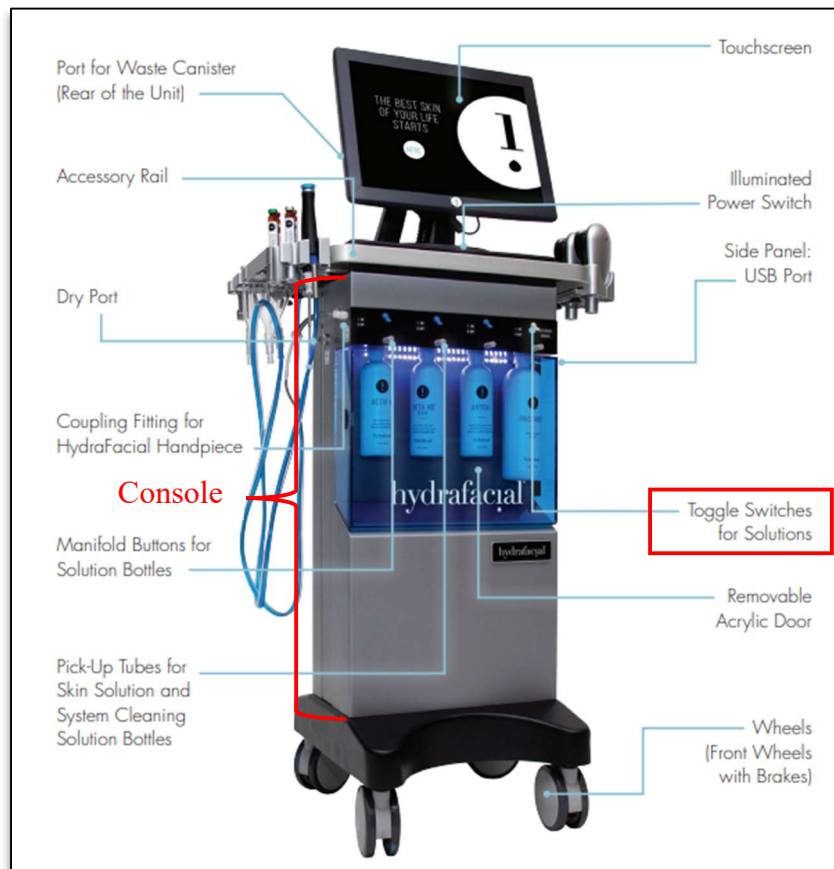
151. As described above, the supply conduit extends from the handpiece assembly to the manifold, which is in fluid communication with the fluid containers (including the first and second fluid containers). As explained below, the manifold in fluid communication with the fluid containers is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

152. The Syndeo IFU explains that the Syndeo includes “solution bottle controls . . . located on the bottom of the screen within the treatment steps.” It further explains that the system “automatically selects and deselects the recommended solution bottle based on the respective treatment step.” A corresponding excerpt from the Syndeo IFU is included below.

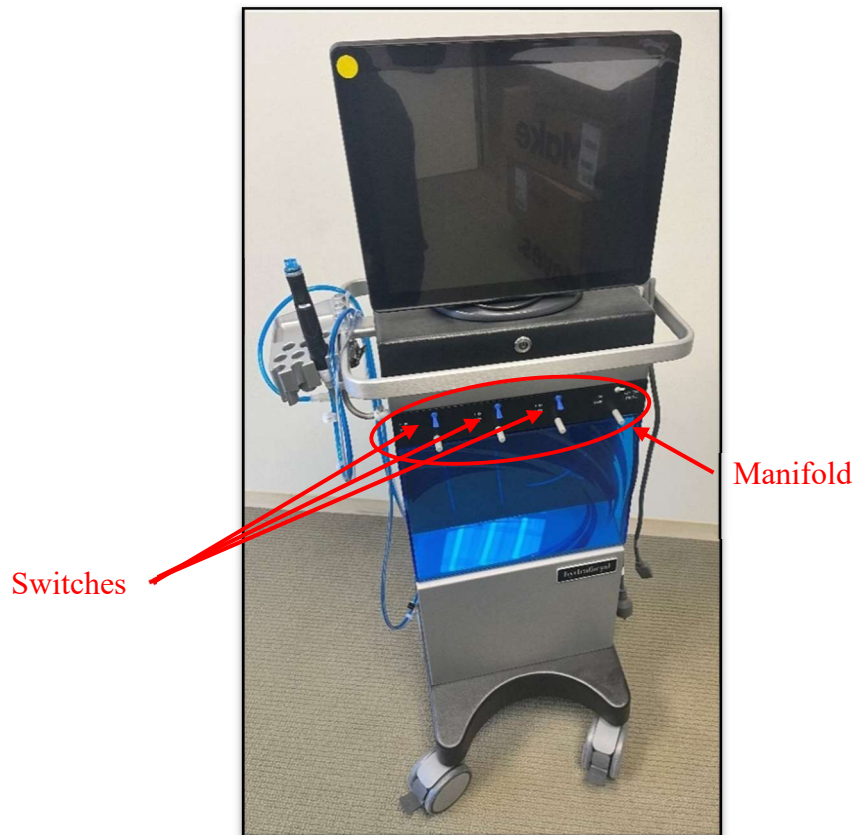
3. The Syndeo system solution bottle controls are located on the bottom of the screen within the treatment steps. The Syndeo system automatically selects and deselects the recommended solution bottle based on the respective treatment step. To override the system selection, simply select and deselect bottles by pressing the buttons on the touchscreen. Long press a button to select multiple bottles at one time.



Ex. 2030 at 14 (Syndeo IFU). In this manner, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.



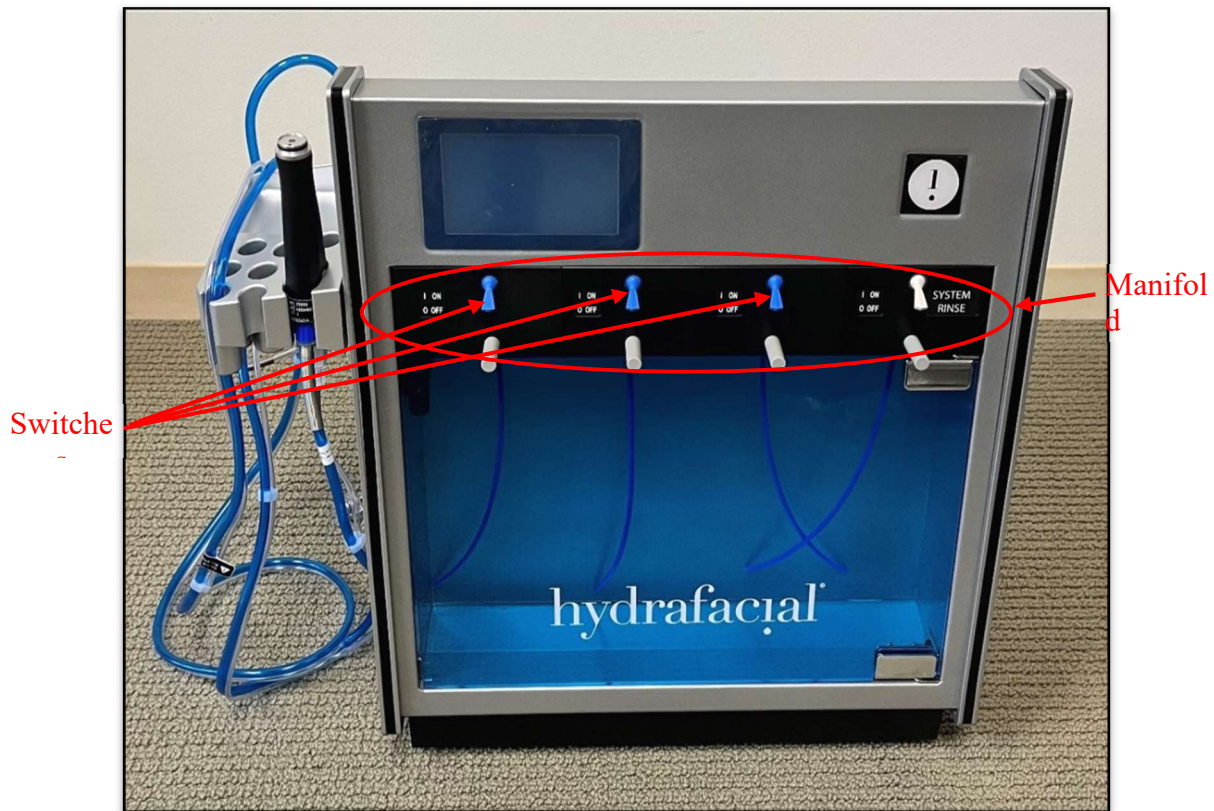
Ex. 2031 at 10 (Elite User Guide).



(Elite)



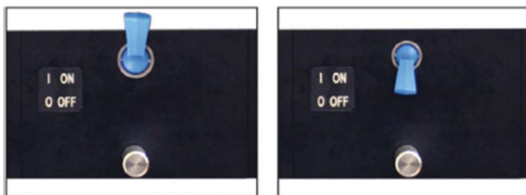
Ex. 2032 at 8 (Allegro IFU).



(Allegro)

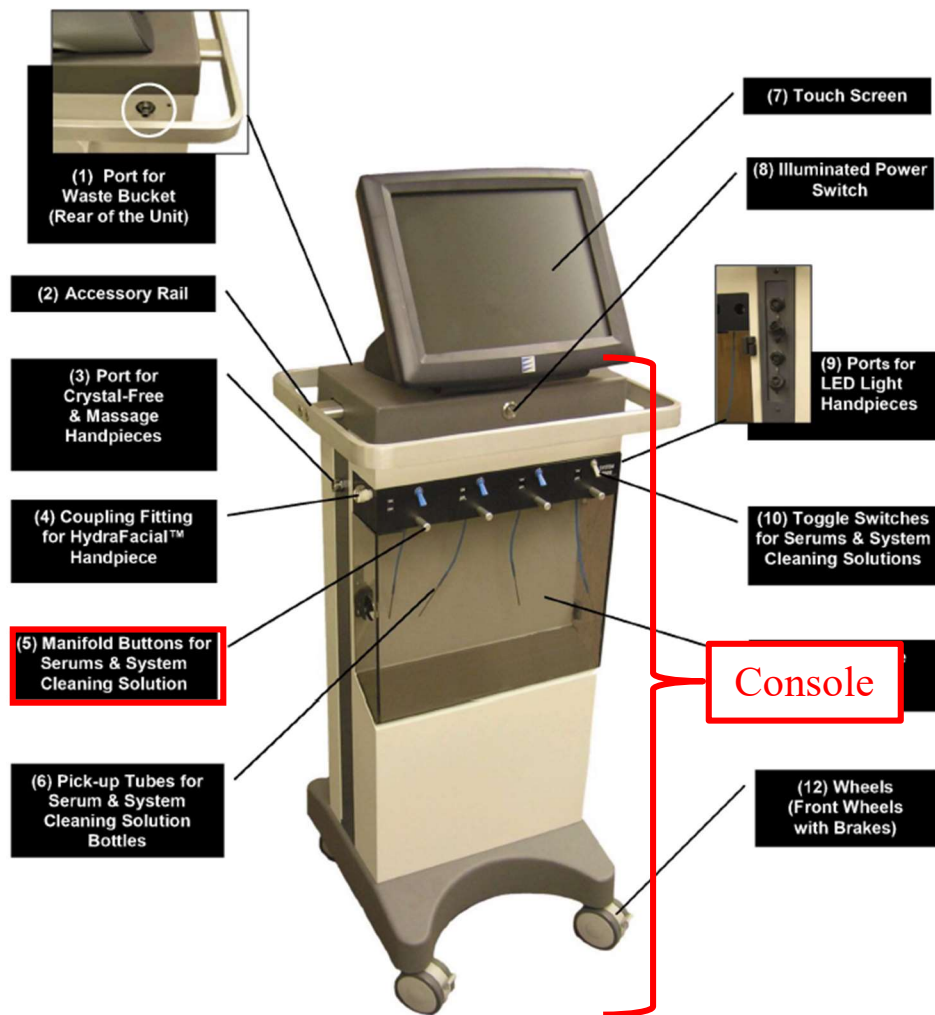
3. The toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle.

Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off while performing procedures.



Ex. 2032 at 11 (Allegro IFU).

153. My review of videos and images of the Tower confirmed its “manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.”



Ex. 2033 at 8 (Tower Owner's Manual).

154. The Tower Owner's Manual confirms my understanding and explains that "[t]he toggle switches control which serum bottle is being used. When a switch is in the OFF position, no fluid will be drawn from that bottle. When a switch is in the ON position, fluid will be drawn from that bottle." *Id.* Thus, for example, when the switch for the first fluid container is ON and the switch for the at least the second fluid container is OFF, treatment fluid will be delivered to the handpiece assembly from the first fluid container only. Thereafter, when the switch for the first fluid

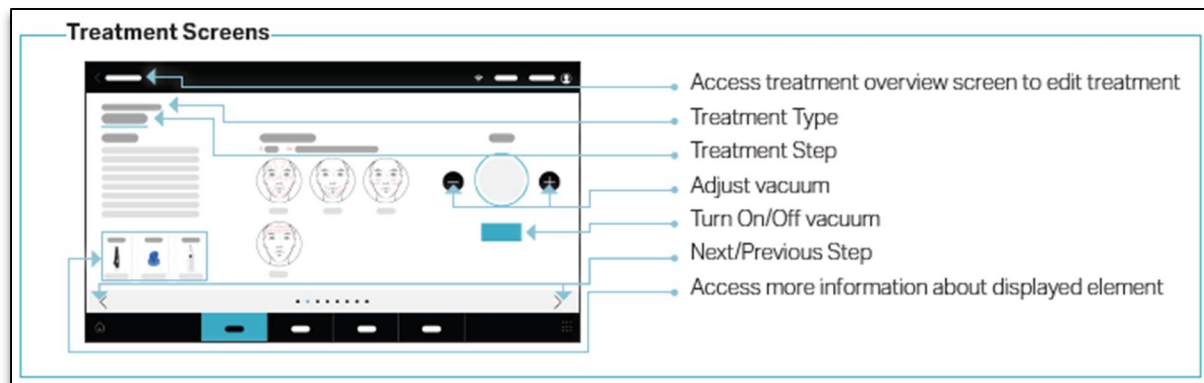
container is OFF and the switch for the at least the second fluid container is ON, treatment fluid will be delivered to the handpiece assembly from the at least the second fluid container only. In this manner, through operation of the toggle switches, the manifold controls a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. Further, the Tower Owner Manual's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." *Id.* at 20.

155. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

6. "a vacuum source;"

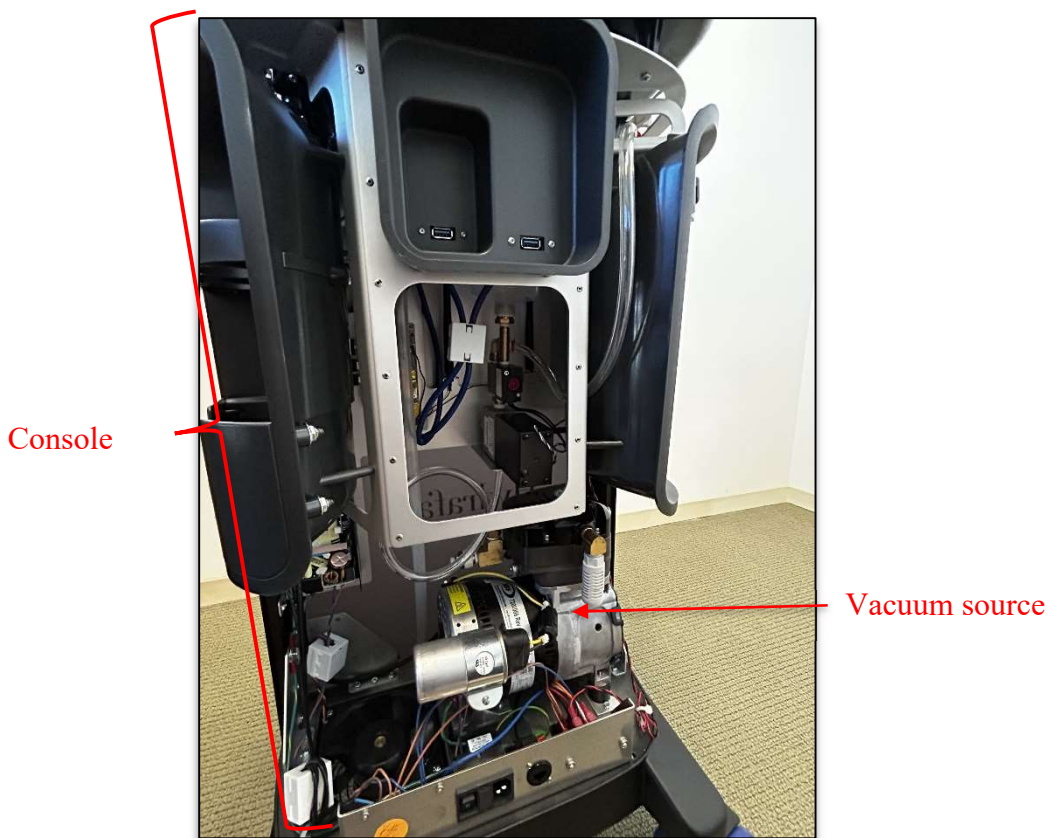
156. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a vacuum source."

157. The Syndeo IFU illustrates and describes turning the vacuum on and off and adjusting the vacuum. An excerpt from the IFU below shows these functionalities on the Syndeo treatment screen.

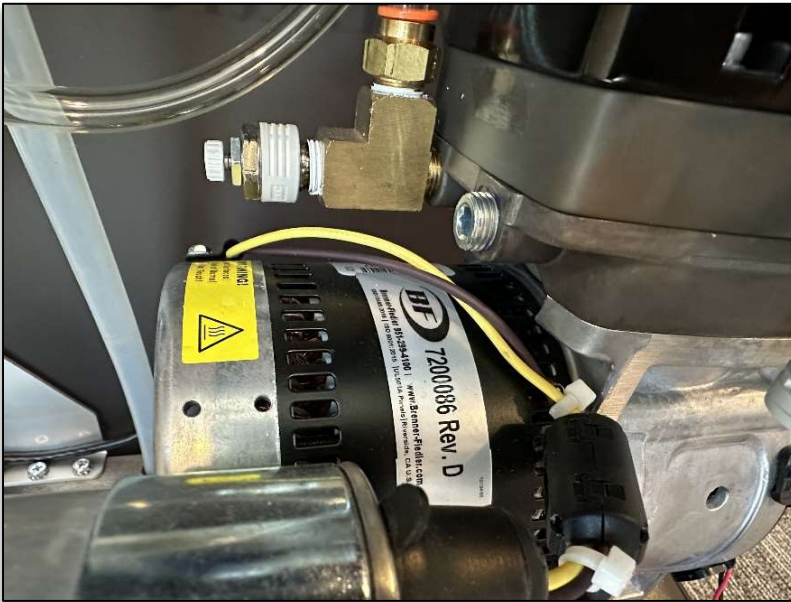


Ex. 2030 at 16 (Syndeo IFU).

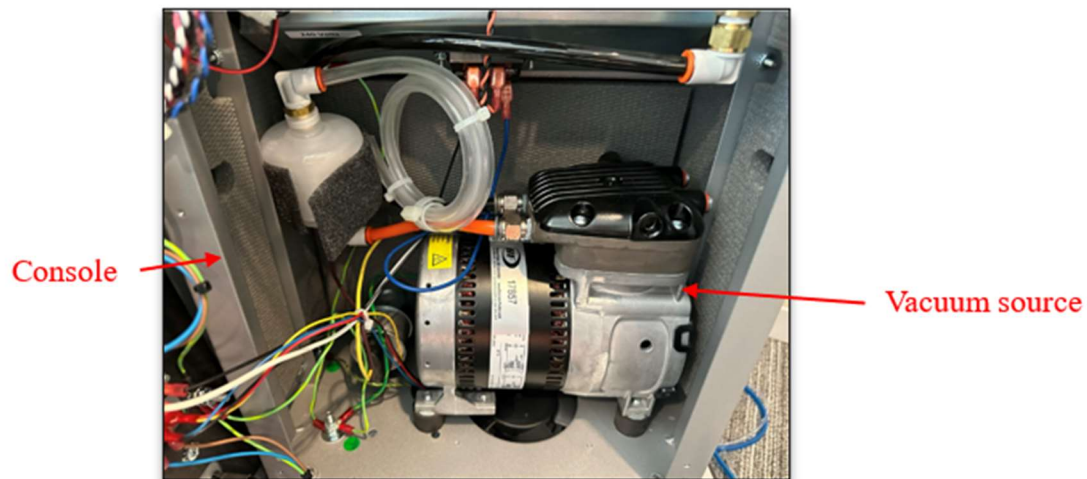
158. As part of my inspect of the each of the Syndeo, Elite, Allegro, and Tower, I opened their respective consoles. In each console, I observed the vacuum source located in the console. As shown in the images below, each of the Syndeo, Elite, Allegro, and Tower includes a vacuum source in the console:



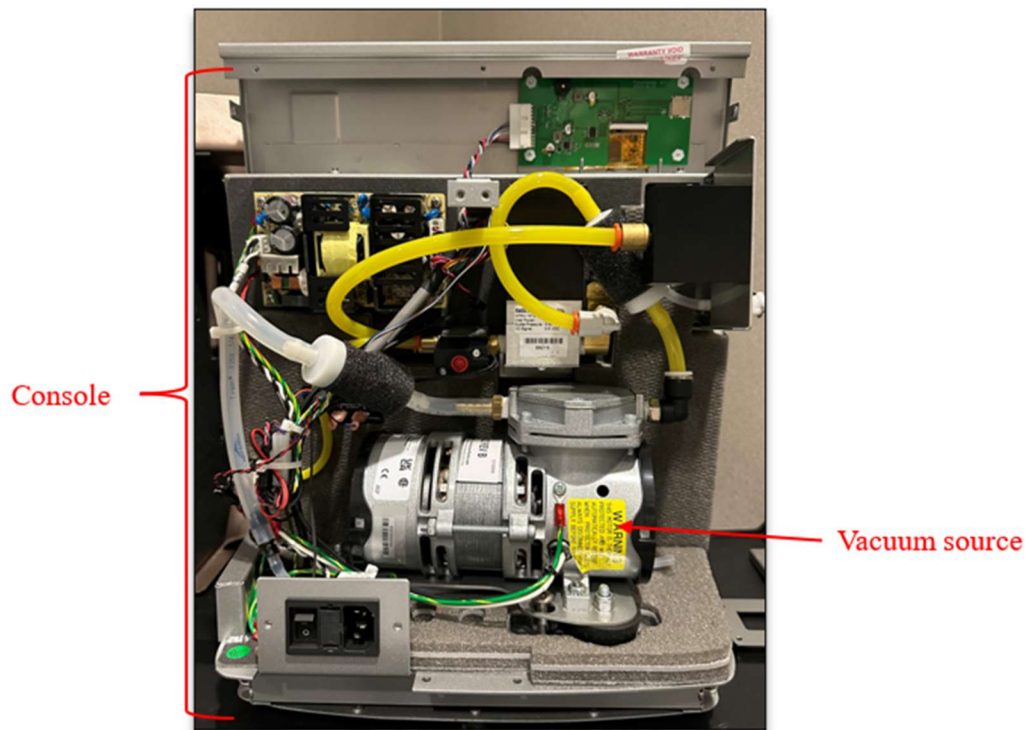
(Syndeo). Further, a closeup image identifying the vacuum source having part number “7200086” is included below.



(Syndeo; vacuum source labeled as part number “7200086”)

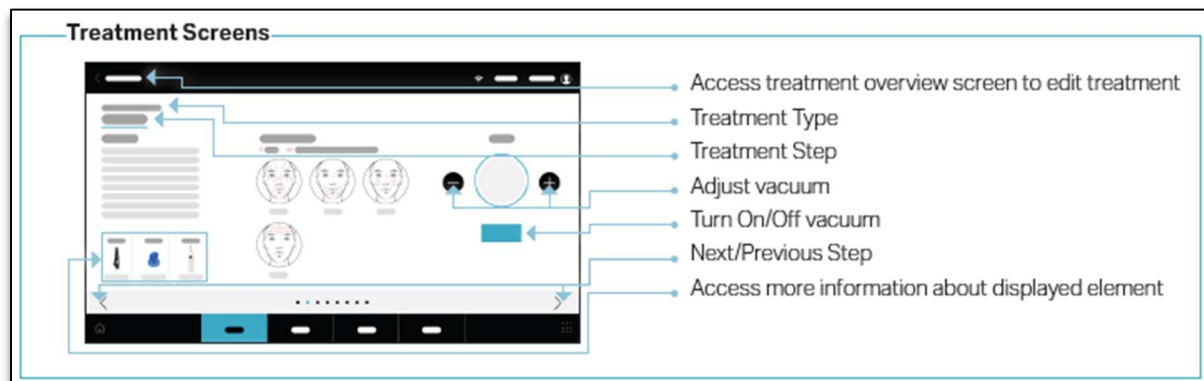


(Allegro).

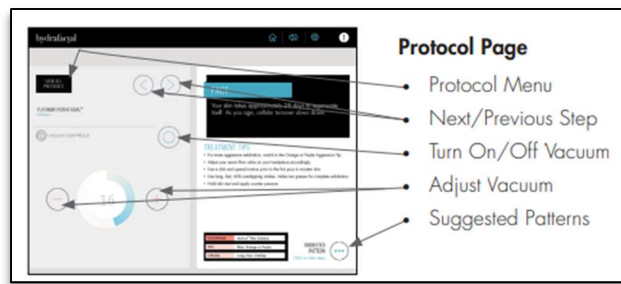


(Allegro).

159. Technical documents for each of the Syndeo, Elite, Allegro, and Tower confirm that a vacuum source is inside of the console. For example, the Syndeo, Elite, and Allegro IFUs describe turning the vacuum on and off and adjusting the vacuum:



Ex. 2030 at 16 (Syndeo IFU).



Ex. 2031 at 16 (Elite User Guide).

Turn The Vacuum On

1. Within each mode, touch the "On" button to start the vacuum.

Turn The Vacuum Off

1. Within each mode, touch the "Off" button to stop the vacuum.

Vacuum Adjustment

1. Within each mode, adjust the vacuum level by pressing the triangular vacuum control buttons. Press the up-arrow button (with the plus sign "+" on it) to increase the vacuum. Press the down-arrow button (with the minus sign "-" on it) to decrease the vacuum.

Note: Use your fingertip, not your fingernail to avoid damage to the screen.

The image shows a close-up of the HydraFacial vacuum control interface. It features a central digital display showing '00'. Above the display are two triangular buttons: a left-pointing triangle with a minus sign '-' and a right-pointing triangle with a plus sign '+'. Below the display are two rectangular buttons: a blue button labeled 'OFF' with a power icon and a blue button labeled 'ON' with a power icon.

Ex. 2032 at 13 (Allegro IFU).

160. The Tower Owner's Manual similarly describes having an adjustable vacuum:

6. Always start the patient at a low vacuum setting and increase the intensity depending on the patient's comfort. Note: each patient's skin condition and pain threshold are different. In light of these variables the suggested setting will vary for each patient. The settings suggested in the on-screen protocols reflect the pressure when the handpiece is occluded against the skin. Every individual's skin is unique. Refer to the recommended settings as a guide, not a guarantee.

Ex. 2033 at 3 (Tower Owner's Manual).

161. My inspection of each of the Syndeo, Elite, Allegro, and Tower devices (in person, via video, or via images) did not identify any external vacuum source,

nor any ports to connect to an external vacuum source. Thus, it is my opinion that the console comprises the vacuum source.

162. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

7. **“a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and”**

163. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has “a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source.”

a. Syndeo

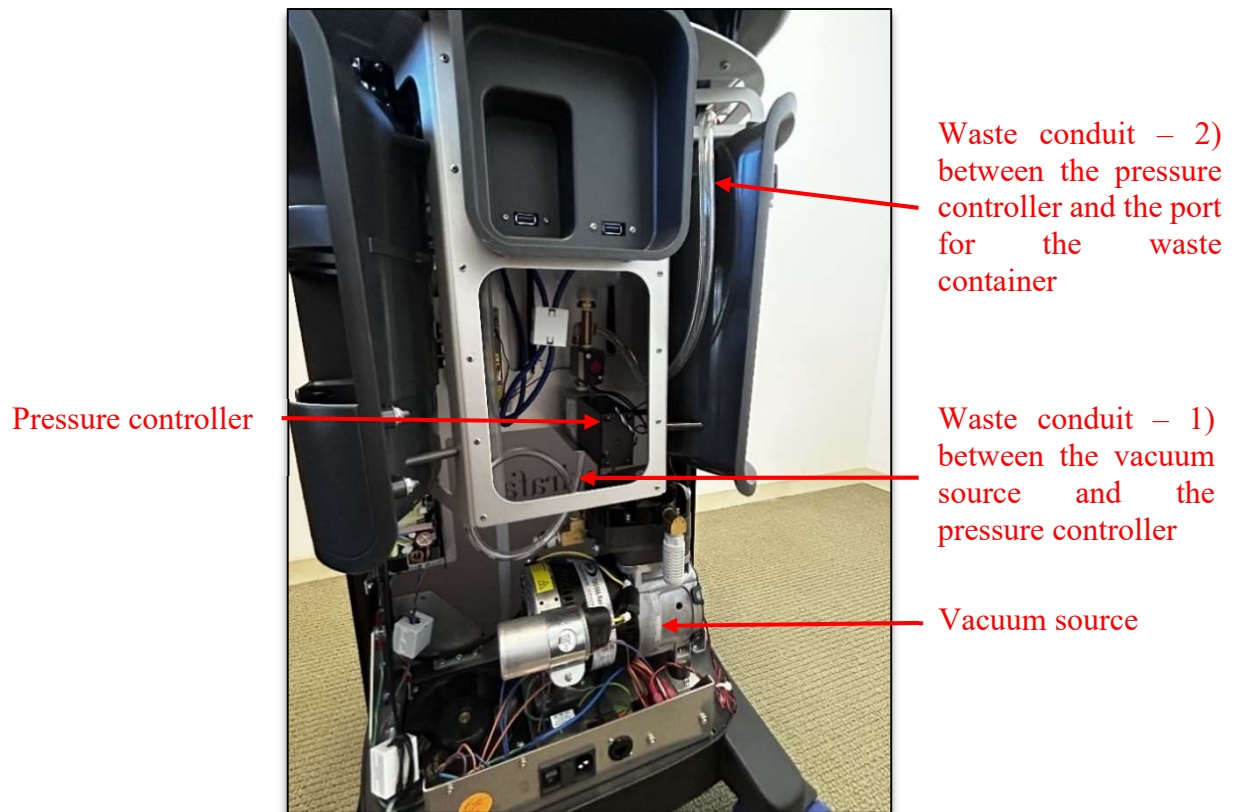
164. I have inspected the Syndeo and have determined that when each of the handpiece assembly, vacuum source, and waste conduit are connected to the console, the tip of the handpiece assembly is in fluid communication with the waste conduit and the waste conduit is operatively coupled to the vacuum source.

165. The handpiece assembly has a “vacuum opening” that is covered by the tip of the handpiece assembly, such that the handpiece assembly vacuums fluids through the tip and into the waste conduit. The annotated photograph below shows the handpiece assembly having a “vacuum opening.”

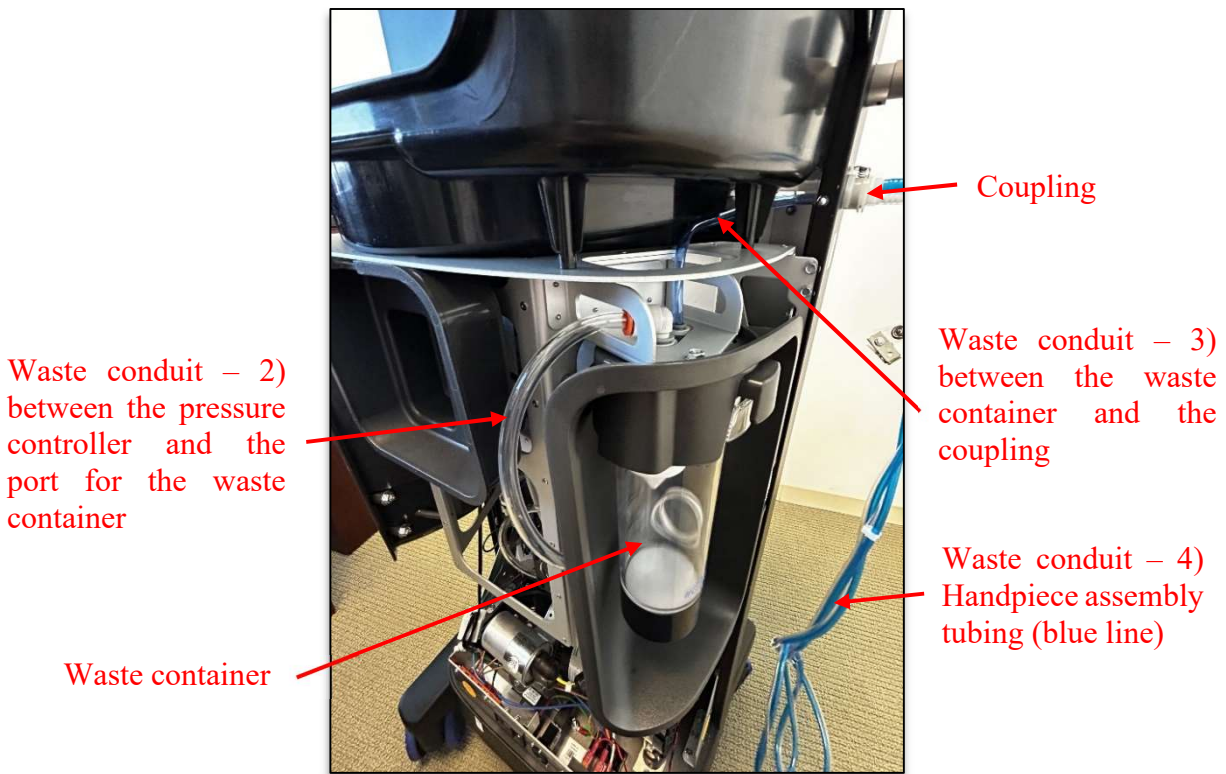


Ex. 2034 at 5 (Handpiece User Guide).

166. The connection to the vacuum source operatively couples the waste conduit and the vacuum source. The annotated photos below show the waste conduit comprising multiple tubing components that extend (1) between the vacuum source and a pressure controller; (2) between the pressure controller and a port for the waste container; (3) between the port of the waste container and the coupling for the handpiece assembly tubing via the waste container and tubing; and (4) between the coupling and the handpiece assembly.



(Syndeo)



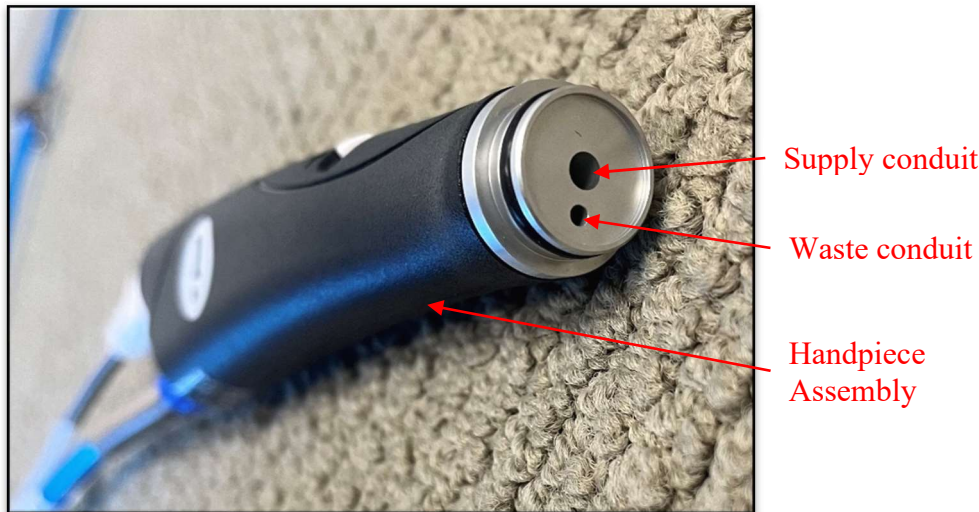
(Syndeo)

167. Below, I have identified the waste conduit and the handpiece assembly that it connects to.



(Syndeo)

168. After the fluid exits the handpiece from the supply conduit, the fluid goes through the handpiece to the waste conduit via an opening on the handpiece assembly, identified below:

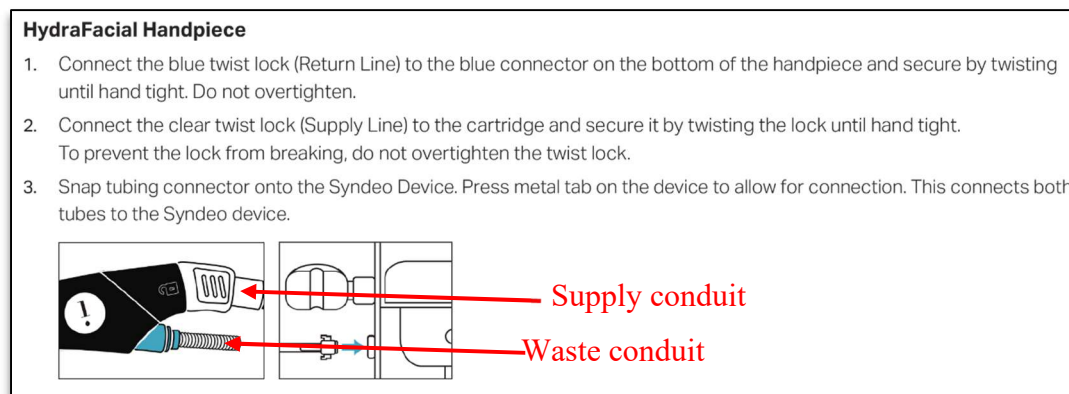


(Syndeo)

169. The Waste Conduit places the handpiece in fluid communication with the vacuum source. I observed that, due to this fluid communication, when the vacuum source is active and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source. Suction from the vacuum source, through the Waste Conduit, the handpiece assembly, the supply conduit, and the manifold of the console allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container.

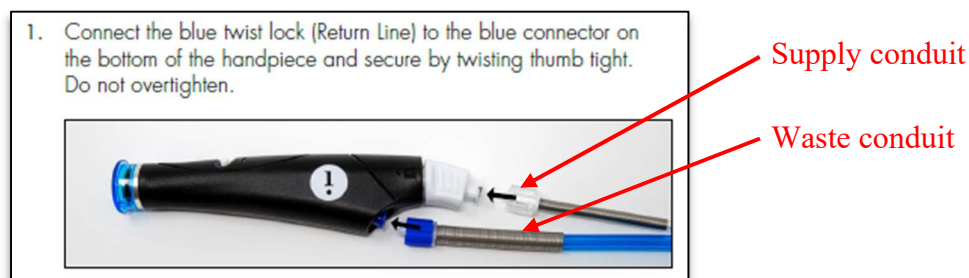
170. The Syndeo IFU confirms the tip of the Syndeo handpiece assembly is configured to be in fluid communication with the waste conduit when the waste conduit is operatively coupled to the vacuum source. To remove waste away from a skin surface of a subject during a skin treatment procedure. The Syndeo IFU

illustrates and describes a “Return Line” attached to the handpiece assembly, wherein the Return Line which serves as a portion of the waste conduit through which the tip of the handpiece assembly is in fluid communication with the vacuum source. For clarity, I have also labeled the supply conduit, which I describe greater detail above in section VII.A.4.



Ex. 2030 at 12 (Syndeo IFU).

171. The Handpiece User Guide also describes the “Return Line” being connected between the handpiece assembly and a waste container (“waste canister”), which is, in turn, connected to and in fluid communication with the vacuum source in the console as shown in the annotated photograph below.



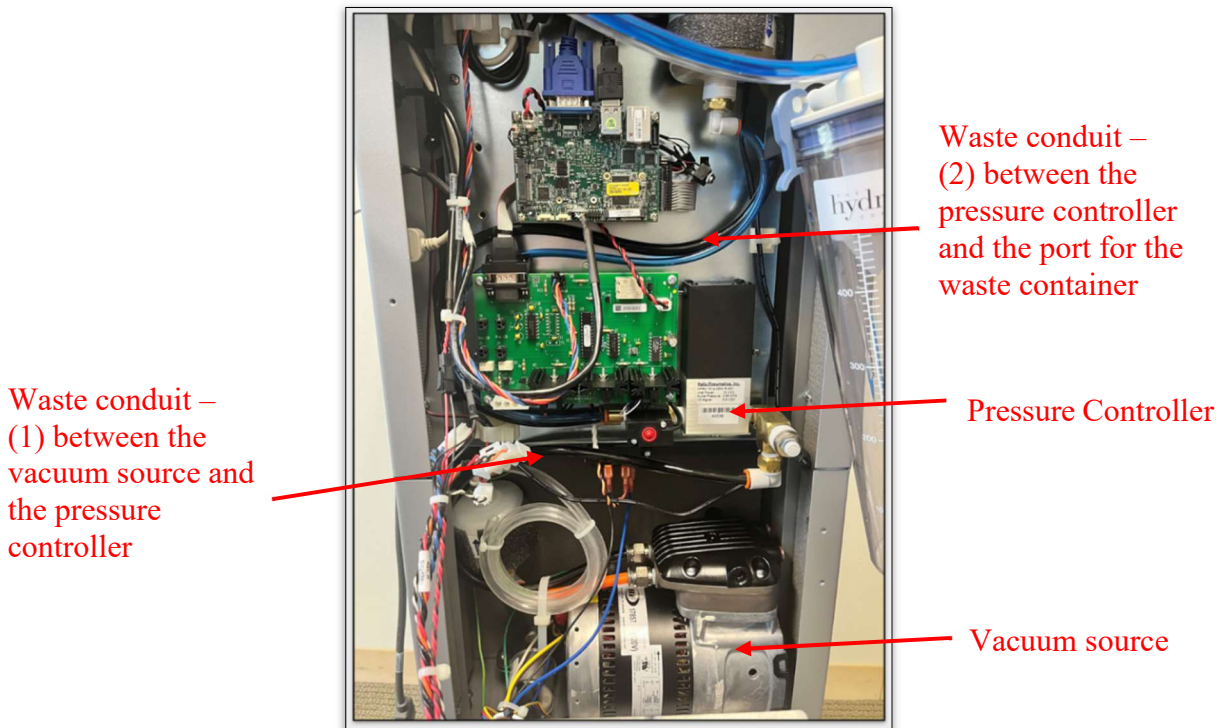
Ex. 2034 at 3 (Handpiece User Guide); *see also* Ex. 2030 at 22 (Syndeo IFU) (“Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister.”).

172. Accordingly, it is my opinion that this limitation is satisfied by the Syndeo.

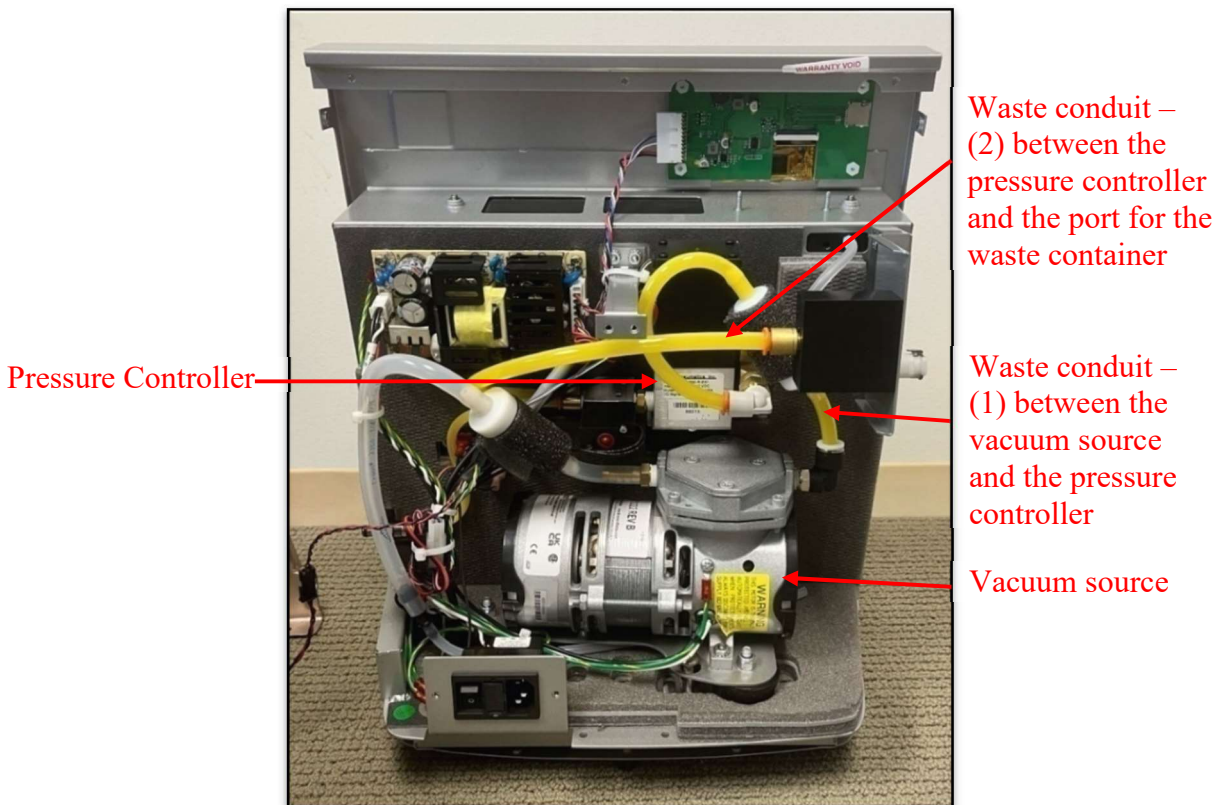
b. Elite, Allegro, & Tower

173. My inspection of the Elite and Allegro, and review of images, videos, and documents for the Tower, confirmed that this limitation is satisfied. As discussed above, the handpiece assembly has a “vacuum opening” that is covered by the tip of the handpiece assembly, such that the handpiece assembly vacuums fluids through the tip and into the waste conduit.

174. The waste conduit comprises multiple tubing components that extend (1) between the vacuum source and a pressure controller; (2) between the pressure controller and a port for the waste container; (3) between the port for the waste container and the tubing of the handpiece assembly via a waste container; and (4) between the coupling and the handpiece assembly. The connection to the vacuum source operatively couples the waste conduit and the vacuum source.



(Elite)



(Allegro)

175. The blue tubing for the handpiece assembly contains the waste conduit.

The waste conduit continues from the port for the waste container on the console through the tubing to the handpiece assembly.

Waste conduit – 3)
between the port for the
waste container and tubing
for handpiece assembly

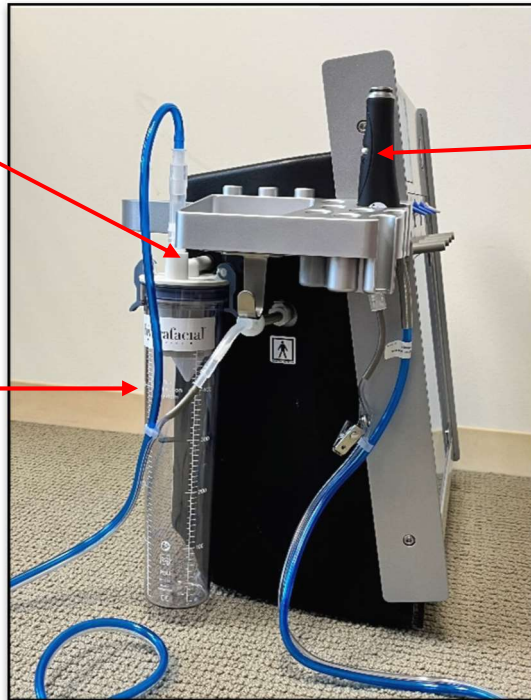
Waste conduit – (4)
Handpiece assembly
tubing (blue line)



(Elite)

Waste conduit – 3)
between the port for the
waste container and
tubing for handpiece

Waste conduit – 4)
Handpiece assembly
tubing (blue line)



Handpiece Assembly

(Allegro)

176. The Tower has the same waste conduit comprised of multiple tubing components. Below, I have annotated image two images of the Tower Device. The first image identifies the handpiece, and the waste conduit tubing to the handpiece assembly. The second image identifies the waste conduit between the port for the waste container and tubing for handpiece assembly.

Handpiece
Assembly



Waste conduit

(Tower)

Waste conduit –
tubing to handpiece
assembly

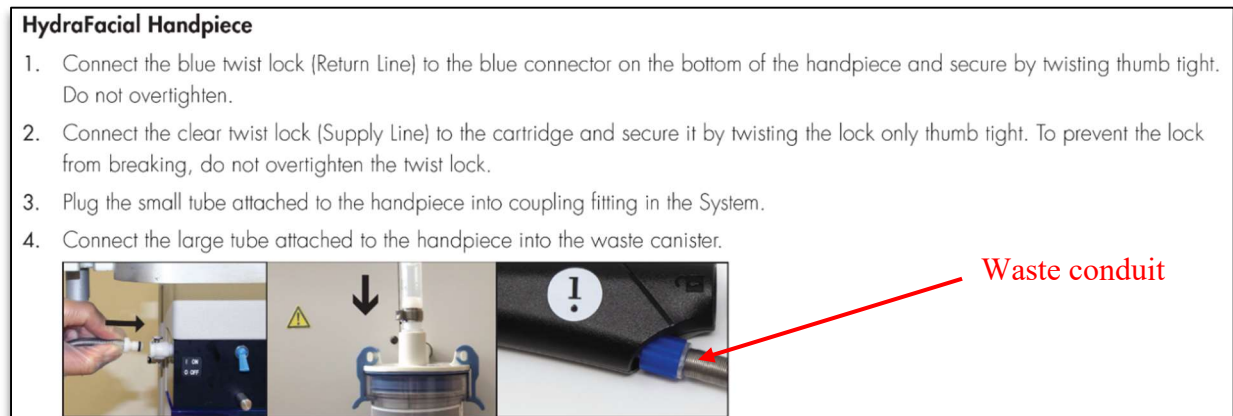


Waste conduit –
waste conduit internal

Waste conduit –
between the port for
the waste container
and tubing for
handpiece assembly

(Tower)

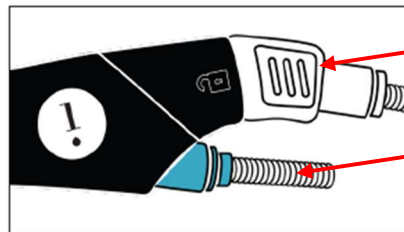
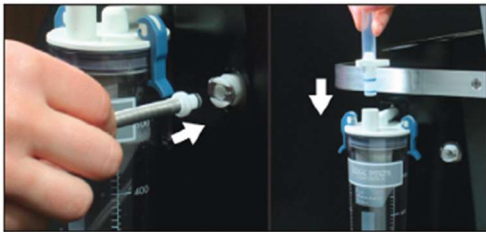
177. Technical documents for the Elite and Allegro confirm that they each include a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source. The Elite and Allegro IFUs illustrate and describe a “Return Line” attached to the handpiece assembly, wherein the Return Line which serves as a portion of the waste conduit through which the tip of the handpiece assembly is in fluid communication with the vacuum source (the “supply conduit” described above is also labeled for reference and clarity in the illustrations below).



Ex. 2031 at 12 (Elite User Guide).

HydraFacial® Handpiece

1. Plug the small tube attached to the HydraFacial® handpiece into coupling fitting.
2. Connect the large tube attached to the handpiece into the waste container.
3. Locate the small tubing with the blue end and connect it to the appropriate end on the handpiece. The blue end corresponds with the blue dot. Twist the knob gently clockwise to secure the tubing.

Supply
conduitWaste
conduit

Ex. 2032 at 9 (Allegro IFU).

178. The Handpiece User Guide also describes the “Return Line” being connected between the handpiece assembly and a waste container (“waste canister”), which is, in turn, connected to and in fluid communication with the vacuum source in the console.

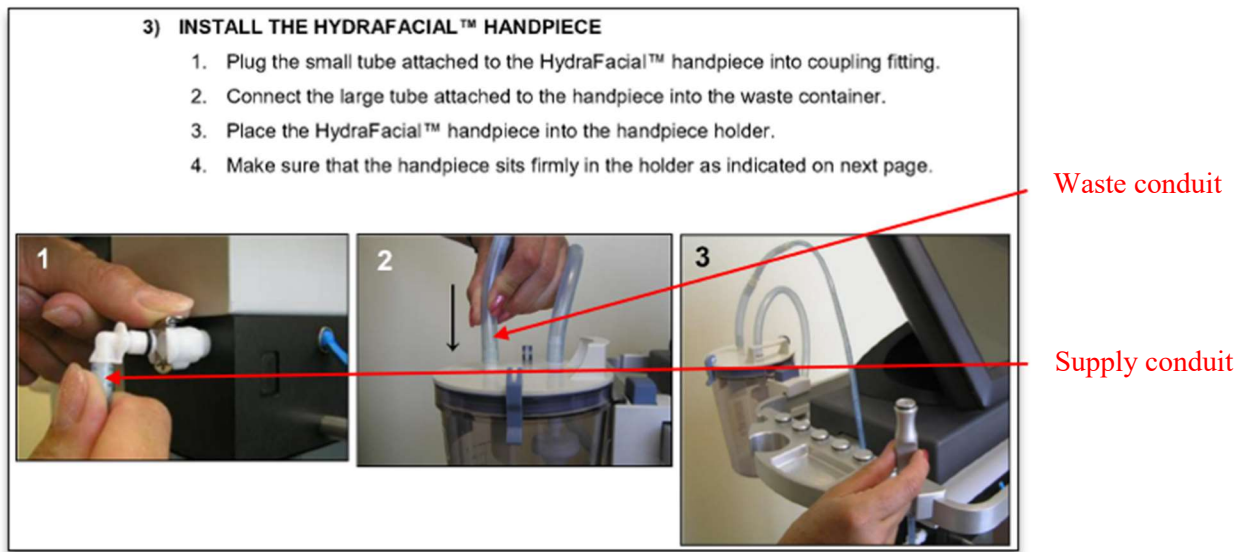


Supply conduit

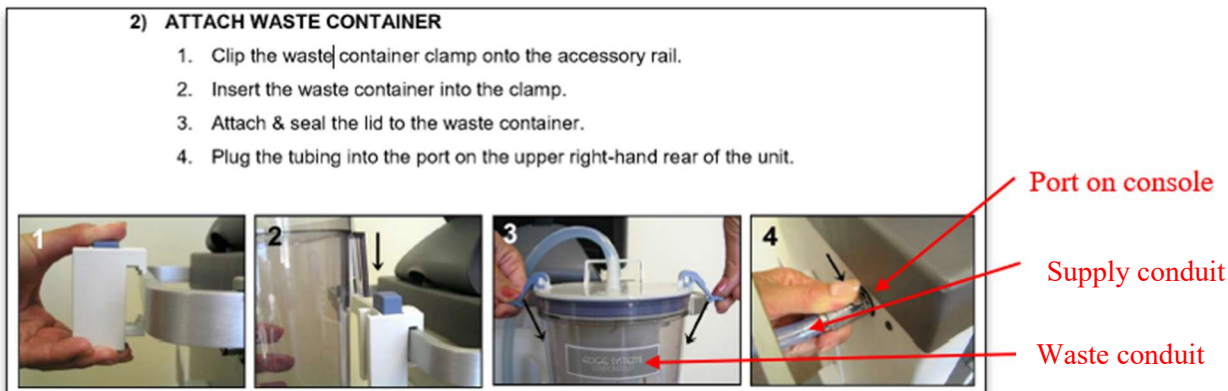
Waste conduit

Ex. 2034 (Handpiece User Guide).

179. In the Tower, the waste conduit referenced in the image below as attaching to both the handpiece and coupling, serves as a portion of the waste conduit and is operatively coupled to the vacuum source.



Ex. 2033 at 10 (Tower Owner's Manual). The waste conduit continues through the waste container and through a port for the waste container on the console, shown below.



Id. at 654 (Tower). As shown in the image above, there is tubing connecting the vacuum source to the port of the waste container, thus placing the handpiece assembly in fluid communication with waste conduit, which is operatively coupled to the vacuum source.

180. Accordingly, it is my opinion that this limitation is satisfied by each of the Elite, Allegro, and Tower.

8. “wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at

least second fluid container to be delivered through the supply conduit to the handpiece assembly; and”

181. In my opinion, each of the Elite, Allegro, and Tower is “configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.”

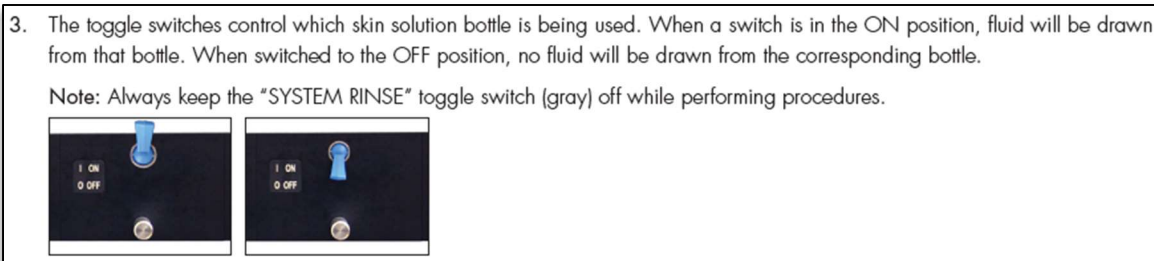
182. As described above, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. As described below, each of the HydraFacial Syndeo, Elite, Allegro, and Tower permits a user to select the treatment material to be delivered through the supply conduit to the handpiece assembly.

183. As explained by the Syndeo, Elite, and Allegro IFUs, the user may select which bottle (and thus which skin solution) is used during treatment by selecting the bottles on the console screen.

3. The Syndeo system solution bottle controls are located on the bottom of the screen within the treatment steps. The Syndeo system automatically selects and deselects the recommended solution bottle based on the respective treatment step. To override the system selection, simply select and deselect bottles by pressing the buttons on the touchscreen. Long press a button to select multiple bottles at one time.



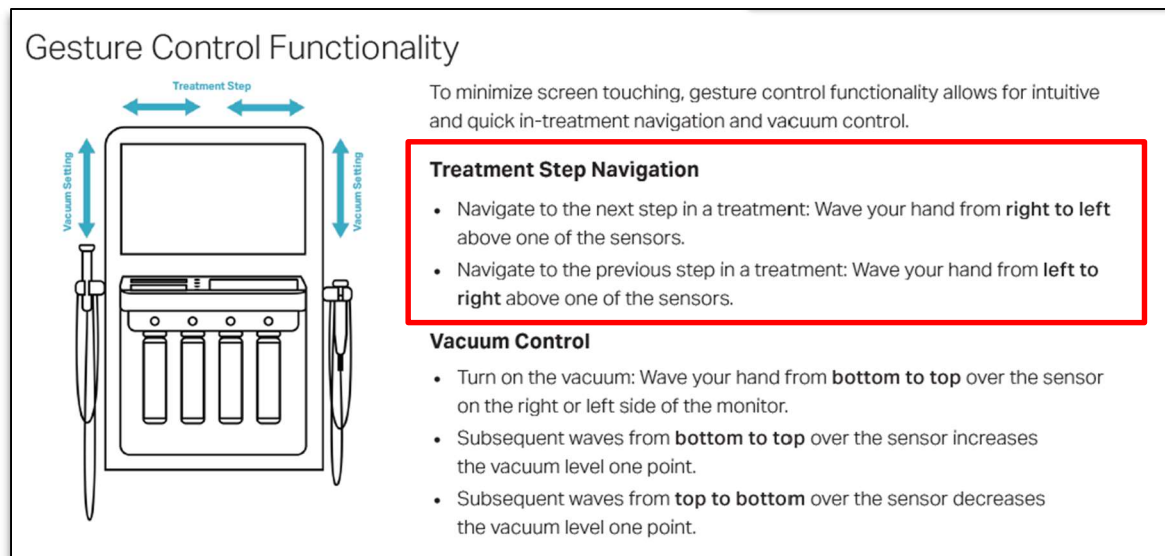
Ex. 2030 at 14 (Syndeo IFU).



Ex. 2031 at 14 (Elite User Guide); *see also* Ex. 2032 at 11 (Allegro IFU).

184. Each of the Elite and Allegro technical documents further states that “[w]hen a switch is in the ON position, fluid will be drawn from that bottle” and “[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle.” Ex. 2031 at 14 (Elite User Guide); *see also* Ex. 2032 at 11 (Allegro IFU). Since the user controls these switches, the HydraFacial Allegro permits a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

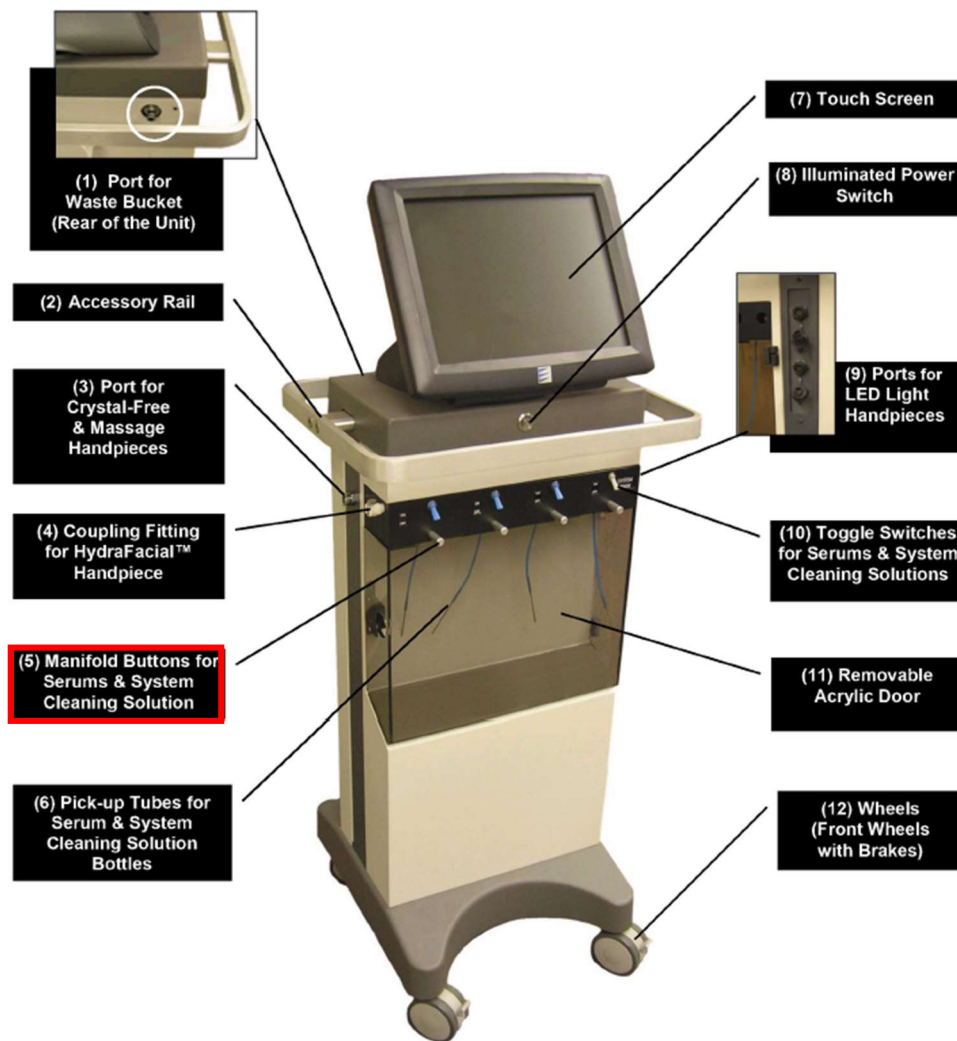
185. The Syndeo IFU also allows a user to select the treatment step—and therefore the treatment material from the first fluid container or the at least second fluid container to be delivered—via “Gesture Control Functionality,” as shown in the annotated image below.



Ex. 2030 at 17 (Syndeo IFU).

186. The Tower Owner's Manual explains that "[t]he toggle switches control which serum bottle is being used. When a switch is in the OFF position, no fluid will be drawn from that bottle. When a switch is in the ON position, fluid will be drawn from that bottle." Ex. 2033 at 8 (Tower Owner's Manual). Thus, for example, when the switch for the first fluid container is ON and the switch for the at least the second fluid container is OFF, treatment fluid will be delivered to the handpiece assembly from the first fluid container only. Thereafter, when the switch for the first fluid container is OFF and the switch for the at least the second fluid container is ON, treatment fluid will be delivered to the handpiece assembly from the at least the second fluid container only. In this manner, through operation of the toggle switches, the Tower permits a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the

supply conduit to the handpiece assembly. Further, the Tower Owner Manual's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." Ex. 2033. at 20.



Id. at 8 (Tower Owner's manual).

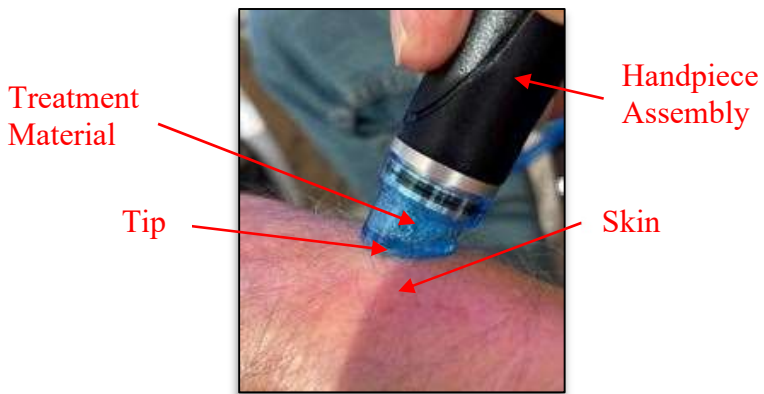
187. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

9. **“wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste**

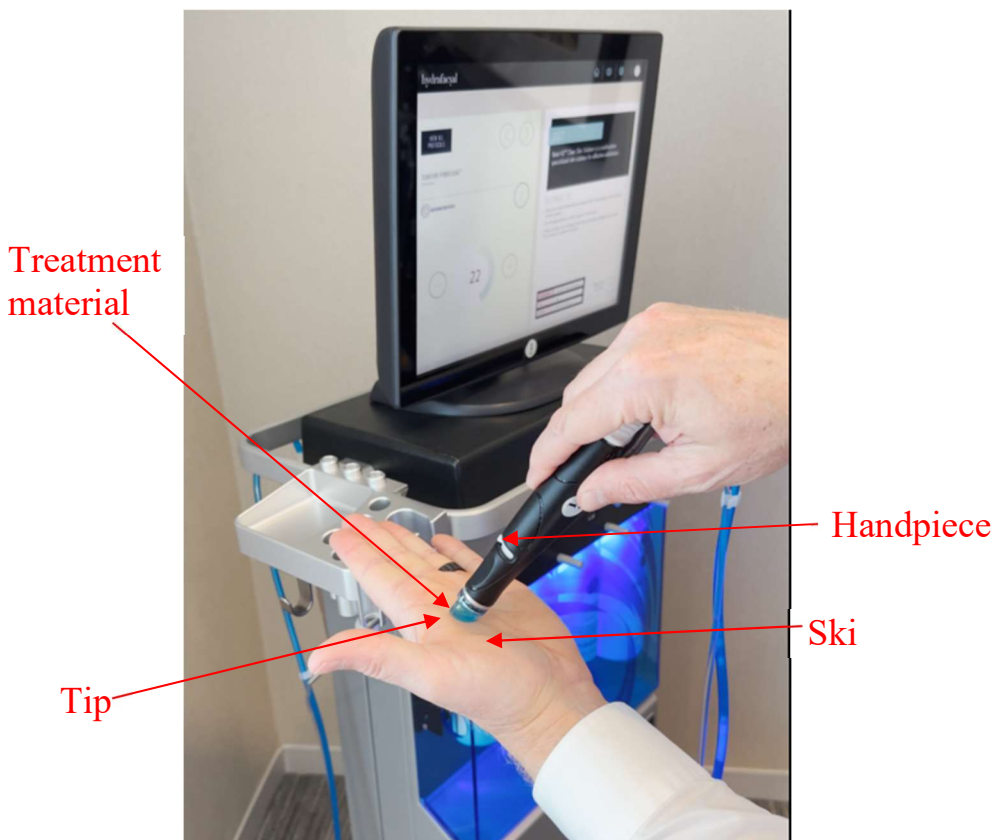
from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.”

188. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has vacuum source wherein “when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.”

189. As explained above, each of the HydraFacial Syndeo, Elite, and Allegro has (1) a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure; (2) a vacuum source operatively coupled to the waste conduit; (3) a handpiece assembly with a tip that is configured to contact a skin surface of a subject during treatment; and (4) a manifold configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit to the handpiece assembly. As shown below, it is the same suction force that removes waste from the skin surface via the waste conduit that also draws treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.



(Syndeo).



(Elite).

190. The Syndeo IFU confirms my understanding that the suction force that removes waste from the skin surface via the waste conduit is the same suction force

that draws treatment material from the first fluid container or the second fluid container to the tip of the handpiece assembly via the supply conduit.

Treatment

Note: Each treatment guides you through the suggested protocol steps, stroke patterns, formulas, and vacuum settings.

1. Cleanse client's face.
2. Place a tip on the handpiece.
3. Turn on the vacuum.
4. Place tip against skin to occlude and dab skin solution onto skin.

Ex. 2030 at 19 (Syndeo IFU).

191. The “Troubleshooting” sections of each of the Syndeo, Allegro, Elite IFUs warns that, “[i]f the canister becomes overfull, a builtin float will occlude the vacuum opening and skin solution flow through the handpiece will cease.” *Id.* at 22. The recommended solution to this situation is to “[e]mpty the waste canister after each service.” *Id.* Thus, the vacuum draws from either the first container or the second container to the handpiece assembly when the tip is pressed against skin.

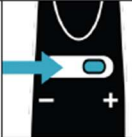
Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations selected at one time.
	Faulty station	If using only one station at a time, deselect current station and try another station. If this corrects the problem please check on the previous station that the internal bottle seal is completely broken and pick up assembly (straw) is fully submerged. Repuncture the bottle if needed.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	Do not let the waste canister fill above 450 mL. If the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.



Ex. 2030 at 22 (Syndeo IFU).

Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.	
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations on the ON position.	
	Faulty station	If using only one station at a time, turn current station off and try another station. If this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged. Repuncture bottle if needed.	
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.	
	Waste canister is full	Do not let the waste canister fill above 450 mL. If the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.	
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.	
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.	

Ex. 2031 at 20 (Elite User Guide).

Low or No Fluid Flow	Toggle Switch	Make sure the switch is on.	
	Empty bottle	Make sure your skin solution bottle is not empty.	
	Improper connection	Make sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station block, and to the waste container. Also, make sure that the lid is firmly attached to the waste container.	
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.	
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign.	
	Leak in the line	Check lines for any kinks or leaks. Repuncture bottle if needed.	
	Faulty station	If using only one station at a time, turn current station off and try another station, if this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged.	
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.	
	Waste canister is full	Do not let the waste container fill above 450 mL. If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste container after each service.	
	Clogging	Flush all stations thoroughly. Make sure the machine is cleaned after each service.	
	Gray Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.	

Ex. 2032 at 17 (Allegro IFU).

192. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

B. The HydraFacial Systems Are Co-Extensive With the Claims

193. I have been informed by counsel that a nexus is presumed between the claimed invention and the objective evidence of secondary considerations of non-obviousness when the product embodies the claimed invention and is coextensive with it.

194. I have been asked to provide expert analysis on whether the Syndeo, Allegro, Elite, and Tower each embodies claim 1 of the '052 Patent and is coextensive with claim 1, sufficient to establish a presumed nexus. As discussed in Section VII.A., above, the Syndeo, Allegro, Elite, and Tower are all multi-container systems for performing a skin treatment procedure having a claimed console including a manifold, a first fluid container and at least a second fluid container, a handpiece assembly comprising a tip, a supply conduit, a vacuum source, and a waste conduit, embodying claim 1 of the '052 Patent.

195. Further, the Syndeo, Elite, Allegro, and Tower are coextensive with the Claim 1 for several reasons. First, Claim 1 is directed to skin treatment systems with specific key features including (1) a console including a manifold; (2) a first fluid container and at least a second fluid container; (3) a handpiece assembly comprising a tip; (4) fluid communication between the manifold and the handpiece assembly;

(5) a vacuum source, and (6) fluid communication between the handpiece assembly and a waste conduit that is operatively coupled to the vacuum source. As discussed in detail above in Section VII.A., the Syndeo, Elite, Allegro, and Tower are skin treatment systems that include the key features recited in the claims.

196. Second, the Syndeo, Elite, Allegro and Tower do not contain other key or driving features that are not claimed. For example, these systems may include red and blue light therapy handpieces. However, the systems are primarily and extensively marketed as a hydrodermabrasion system, rather than light therapy devices. *See, e.g.*, Ex. 2038 (Tower), Ex. 2039 (Tower), Ex. 2040 (Tower), Ex. 2041 (Tower), Ex. 2042 (Tower), Ex. 2043 (Tower), Ex. 2044 (Elite), Ex. 2045 (Elite), Ex. 2046 (Elite), Ex. 2047 (Allegro). I understand that the red and blue light therapy handpieces are not particularly significant to the Syndeo, Elite, Allegro, and Tower, as they are unrelated to hydrodermabrasion, and the effects could be achieved using less expensive machines. *See, e.g.*, Ex. 2015 (handheld red, blue and infrared light treatment device sold for \$299, available at <https://www.celluma.com/products/celluma-pod>). Thus, the features of the Syndeo, Elite, Allegro, and Tower that are significant are the features coextensive with Claim 1 of the '052 Patent.

197. Thus, in my opinion, a nexus is presumed between the secondary considerations and the Syndeo, Elite, Allegro, and Tower.

C. Independent of the Presumption, a Nexus Exists Between the Objective Indicia and the '052 Patent Claims

1. The Nectre Was HydraFacial's Single-Container Hydrodermabrasion System

198. I understand that, in May 2008, HydraFacial launched a hydrodermabrasion system known as the HydraFacial Nectre ("Nectre"). *See, e.g.*, Ex. 2035, Ex. 2036, Ex. 2037. I understand that HydraFacial stopped selling the Nectre in 2013. Unlike the Tower, Elite, Allegro, and Syndeo, the Nectre was a single-container hydrodermabrasion system that lacked a block that could receive fluid from multiple connected containers.

199. In my opinion, the Nectre meets the limitations of Claim 1 that are not dependent on the device having multiple containers connected to the manifold of the console. Below is an analysis of Claim 1 of the '052 Patent.

Exemplary Claim 1

200. Claim 1 recites as follows:

1. A system for performing a skin treatment procedure, the system comprising:
 - a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;
 - a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;
wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and
a vacuum source;
a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and
wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and
wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

I address each limitation of this claim below.

a. **“A system for performing a skin treatment procedure, the system comprising:”**

201. In my opinion, the Nectre is “A system for performing a skin treatment procedure.”

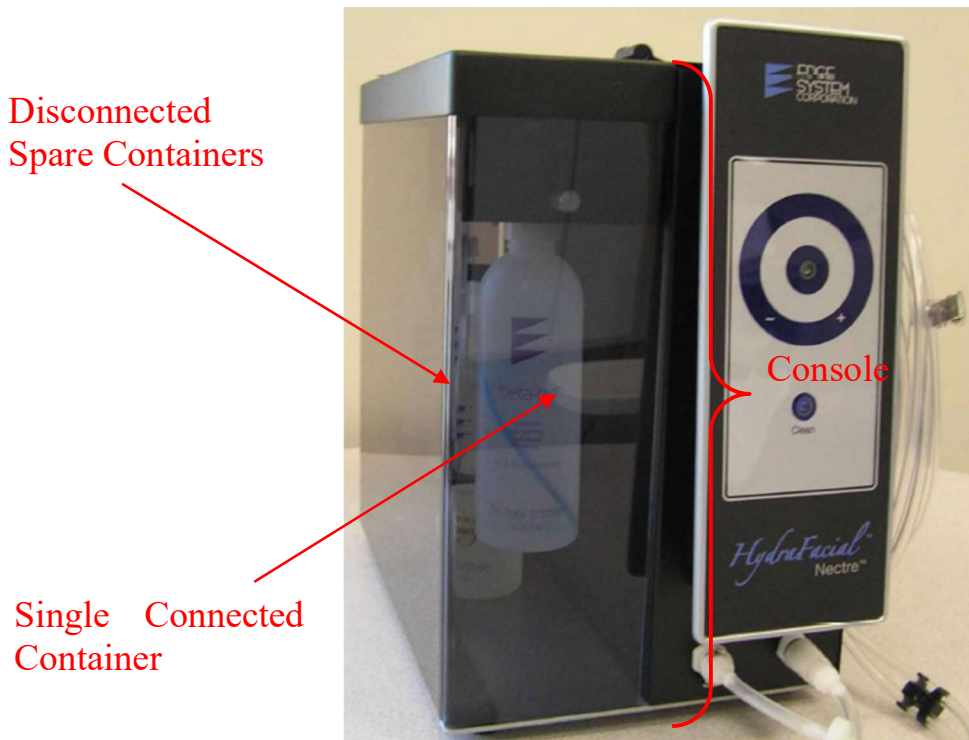
202. The Nectre User’s Manual describes the Nectre as “a revolutionary breakthrough in aesthetic technology” and explains that it is “the next generation of exfoliation and skin rejuvenation.” Ex. 2036 at 4. The User Manual identifies the Nectre as a “USA FDA Class I exempt device” where the intended use is “to perform

dermabrasion (or exfoliation) using mechanical abrasion and water” and to “introduce[e] topic ‘dermaceuticals’ . . . during treatment.” *Id.*

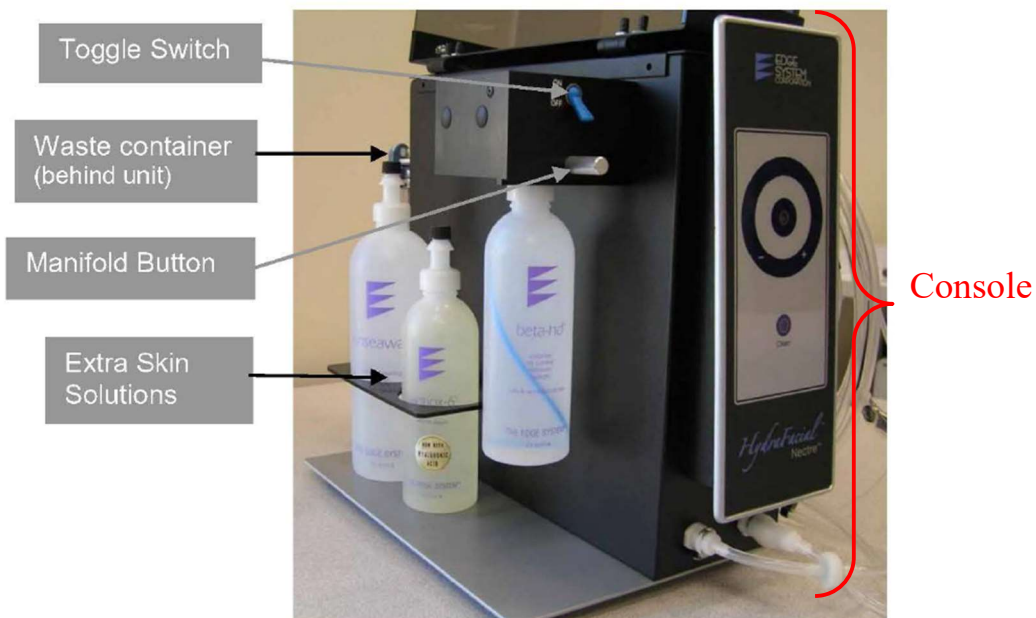
- b. **“a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;”**

203. In my opinion, the Nectre has a console, but lacks “a manifold, the manifold being in fluid communication with a first fluid container **and at least a second fluid container**, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid.”

204. As shown in the images and schematic below, the console is only configured to be in fluid communication with a single fluid container.



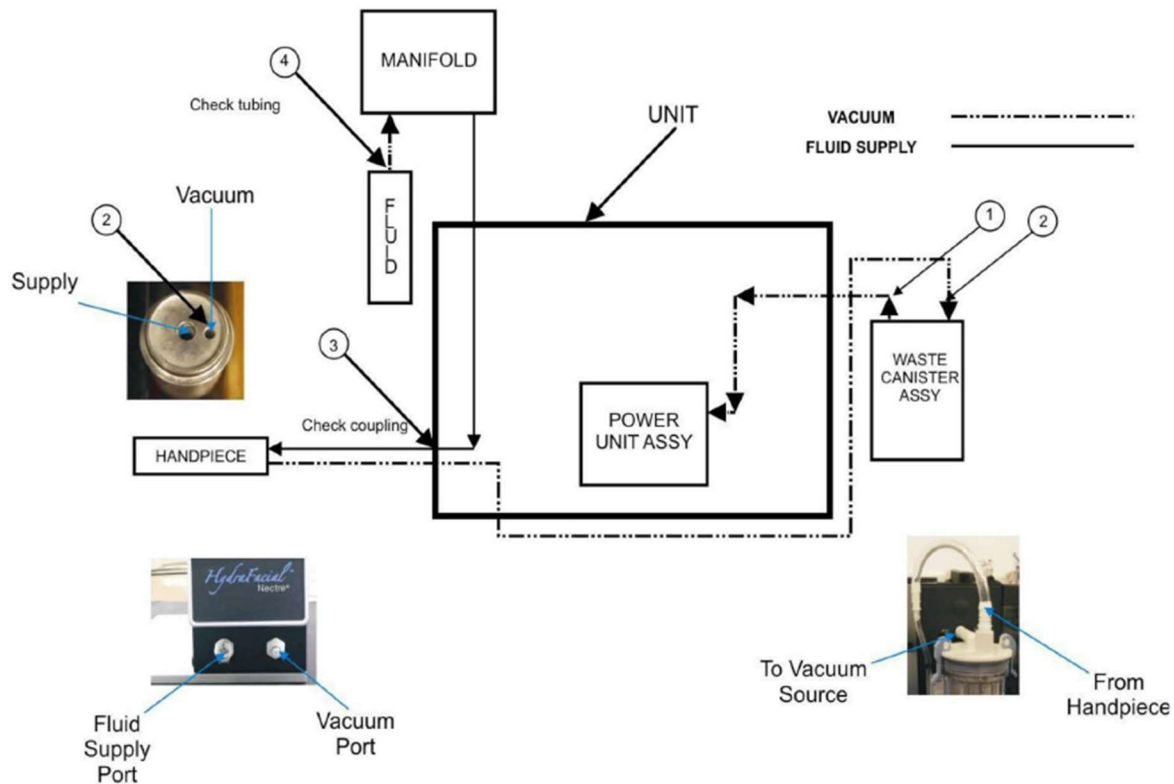
Ex. 2035 at 1 (Nectre Owner's Manual).



Ex. 2036 at 11 (Nectre User Manual)⁴.

⁴ Although the User Manual refers to “manifold buttons” and a “manifold” in the device, a POSA would not recognize this structure as a manifold, since this structure

205. Schematics for the Nectre confirm that only a single fluid container may be connected to the console at a time.



Ex. 2037 at 6 (Nectre User Manual).

206. Users are instructed to connect the single container to the console, as shown below:

is not configured to be in fluid communication with multiple fluid sources at a time. In any event, I will refer to this feature of the Nectre as a “manifold” to maintain consistency with the claim.

4) INSTALL SKIN SOLUTION BOTTLES

1. Open the door on the side of the unit from the bottom.
2. Remove the small black cap off the skin solution bottle and use the puncture tool to pierce the seal inside the bottle. Move the tool in a circular motion to enlarge the opening in the seal so the pickup tube slides in easily.
3. Insert the pickup tube into the unsealed bottle.
4. Press & hold the manifold button and insert the bottle into the manifold, and then release the button. Be sure the bottle is securely attached before releasing it.
5. Place additional bottles of skin solution in the holders behind the skin solution port.



Ex. 2036 at 12 (Nectre User Manual).

- c. **“a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;”**

207. In my opinion, the Nectre has “handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject.”

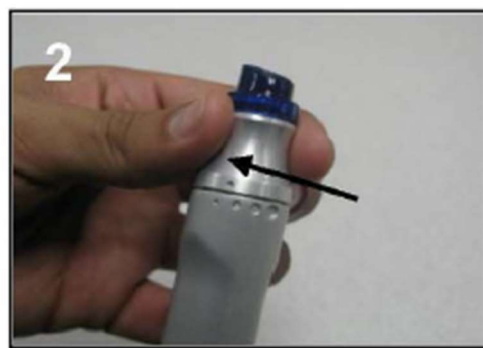
208. The Nectre includes a handpiece assembly, as shown in the images below.

HydraFacial Nectre			
UNIT 	HANDPIECE ASSEMBLY 	WASTE CONTAINER ASSEMBLY 	
	SKIN SOLUTIONS 	CLEANING CAP 	STEM EXTRACTOR 
HYDROPEEL® TIPS 		PUNCTURE TOOL 	

Ex. 2036 at 12 (Nectre User Manual).



1
Increase flow
Counterclockwise



2
Decrease flow
Clockwise

Id. at 16.

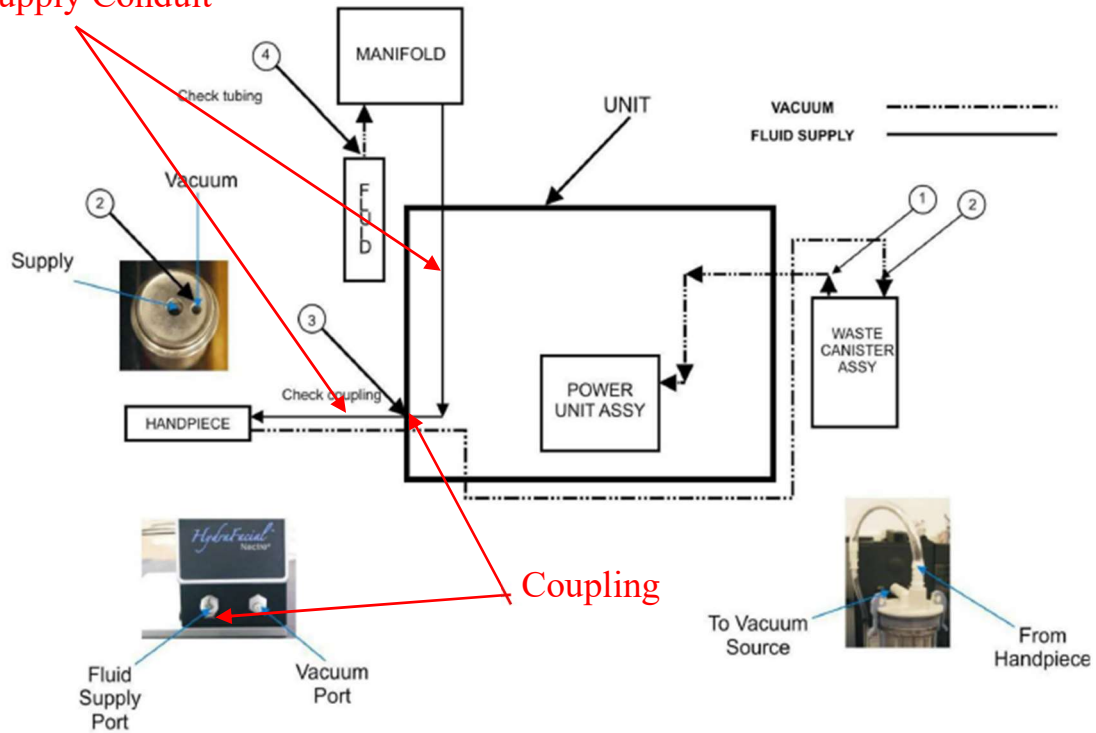
209. In addition, the User Manual confirms that the handpiece assembly configured to contact a skin surface, instructing users to “[d]o a sensitivity test on the neck by the earlobe[.]” Ex. 2036 at 7 (Nectre User Manual); *see also supra* at Section VII.C.1.a. One of the fixes for no or low fluid flow to the handpiece assembly is to “[m]ake sure the HydroPeel plastic tip is firmly installed onto the HydraFacial handpiece.” *Id.* at 21.

- d. **“a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;”**

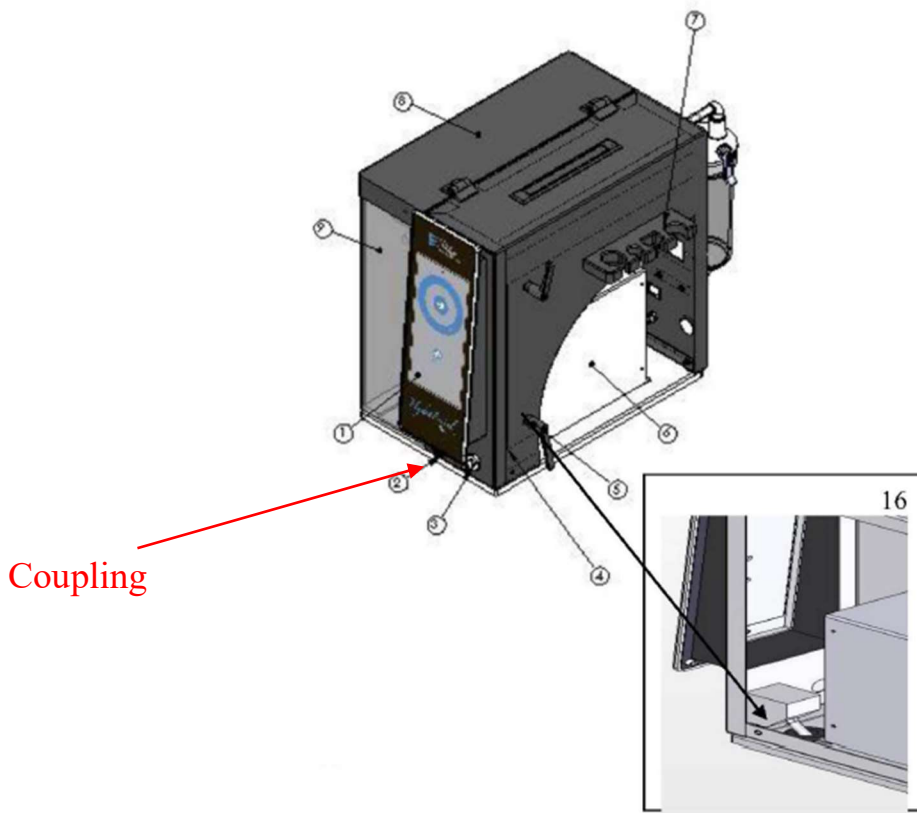
210. In my opinion, the Nectre has “a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly” and lacks a “manifold of the console” as discussed above in section VII.C.1.b.

211. As shown in the schematic and image below, a supply conduit extends internally to the handpiece assembly through a coupling.

Supply Conduit

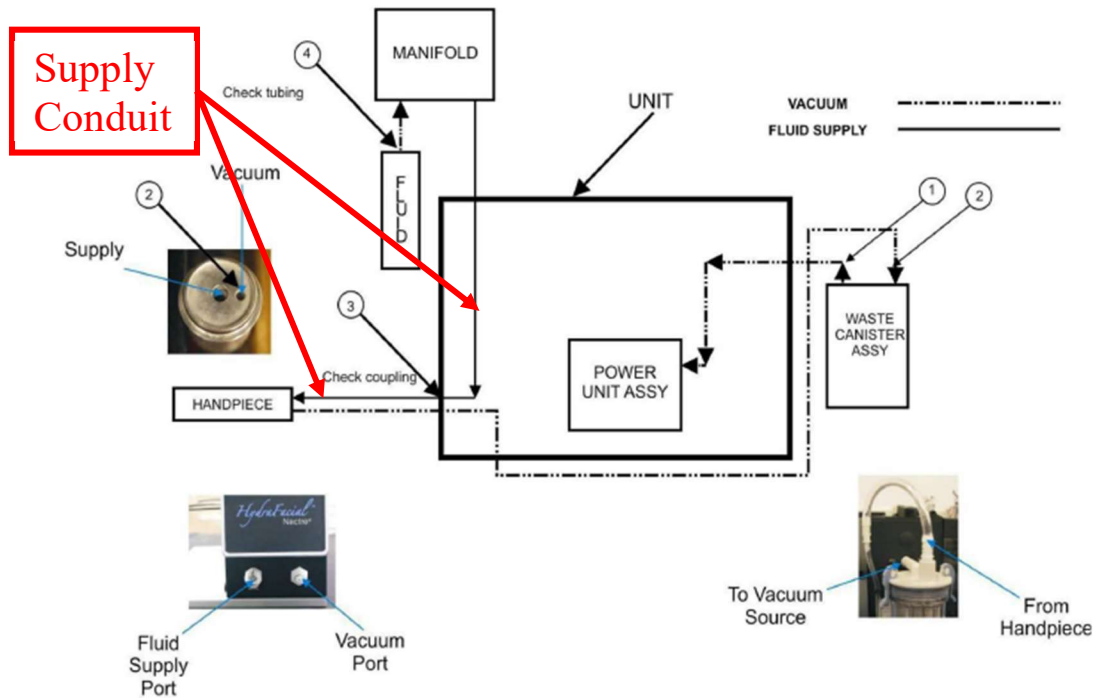


Ex. 2037 at 6 (Nectre Service Manual).



Id. at 7.

212. As shown in the schematic and image below, a supply conduit places the console in fluid communication with the handpiece assembly.

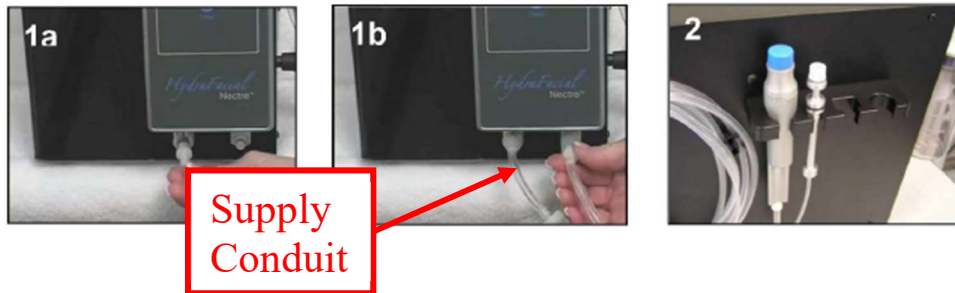


Ex. 2037 at 6 (Nectre Service Manual). The image above shows a “coupling” where tubing from the handpiece assembly connects to the console (the tubing containing the supply conduit).

213. The User Manual instructs a user to connect the “handpiece tubing” (containing part of the “supply conduit”) to the console of the Nectre. Because the handpiece tubing (supply conduit) is connected to the handpiece, the distal end of the supply conduit is coupled to the handpiece assembly.

3) INSTALL THE HYDRAFACIAL HANDPIECE

1. Connect the quick disconnect fittings on the handpiece tubing to the corresponding fittings on the front of the machine. You will hear a click when they are securely attached.
2. Place the handpiece into the tool holder on the right side of the unit.
3. Always place the handpiece in the tool holder when the handpiece is not in use.



Ex. 2035 at 13 (Nectre Owner's Manual).

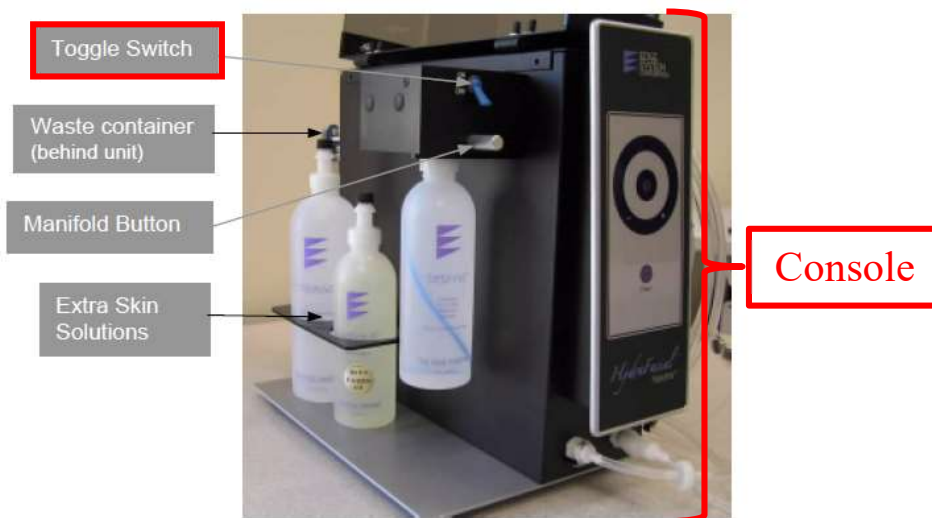
- e. **“wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and”**

214. In my opinion, the HydraFacial Nectre is configured to control a flow of treatment material from the first fluid container [] through the supply conduit” but does not have a “manifold [that] is configured to control a flow of treatment material **from the first fluid container and at least the second fluid container** through the supply conduit.”

215. To the extent the HydraFacial Nectre has any type of a “manifold,” it is configured to control a flow of treatment material from the single connected fluid container, and not an at least the second fluid container, through the supply conduit.

216. As described above, the supply conduit extends from the handpiece assembly to where the single fluid container connects to the console, which is in

fluid communication with the fluid containers. *See* section VII.B.c, *supra*. As explained below, the self-purported “manifold” (block component where the fluid containers connect to the console) in fluid communication with a single fluid container is configured to control a flow of treatment material from that fluid container through the supply conduit.



Ex. 2036 (Nectre User Manual) at 13.

217. The Nectre’s User Manual shows a toggle switch on the block component where the fluid container connects to the console to control the flow of treatment material from the fluid containers.

218. The Nectre’s User Manual and Owner’s Manual caution that “[t]he toggle switch controls whether the skin solution is being drawn from the bottle.” Ex. 2036 at 14 (Nectre User Manual) Ex. 2035 at 13 (Nectre Owner’s Manual).

Note: The toggle switch controls whether the skin solution is being drawn from the bottle.

To use bottled skin solution:

1. Flip toggle switch to the ON position
2. The solid cartridge should be in the cartridge handpiece

To use skin solutions from the vial:

1. Flip the toggle switch to the OFF position
2. A skin solution cartridge must be in the cartridge handpiece.

Id.

219. The User Manual also instructs a user to “[a]lways flip the toggle switches to the OFF position when not in use to prevent skin solution from siphoning out of the handpiece.” Ex. 2036 at 15 (Nectre User Manual). Thus, the HydraFacial Nectre is configured to control a flow of treatment material from the single connected fluid container, and not an at least the second fluid container, through the supply conduit via the toggle switches on the self-described “manifold.”

f. “a vacuum source;”

220. In my opinion, the HydraFacial Nectre has “a vacuum source.”

221. The Nectre User Manual provides instructions for how to turn on/off the vacuum source and adjust vacuum intensity.

2) VACUUM ON/OFF AND ADJUSTMENT

To Turn The Vacuum ON And Adjust Vacuum Level:

1. Tap the power switch  to start the vacuum. The vacuum level default setting is the 4th dot (1 o'clock position). The power indicator light will change to blue, and the first four vacuum level indicator lights will be illuminated.
2. To increase or decrease the vacuum level, either
 - Glide your finger along the vacuum adjustment to the desired level
 - OR-
 - Tap the desired vacuum level position.
3. See your **Service Protocol Manual** for suggested settings for various skin types.



Default vacuum setting



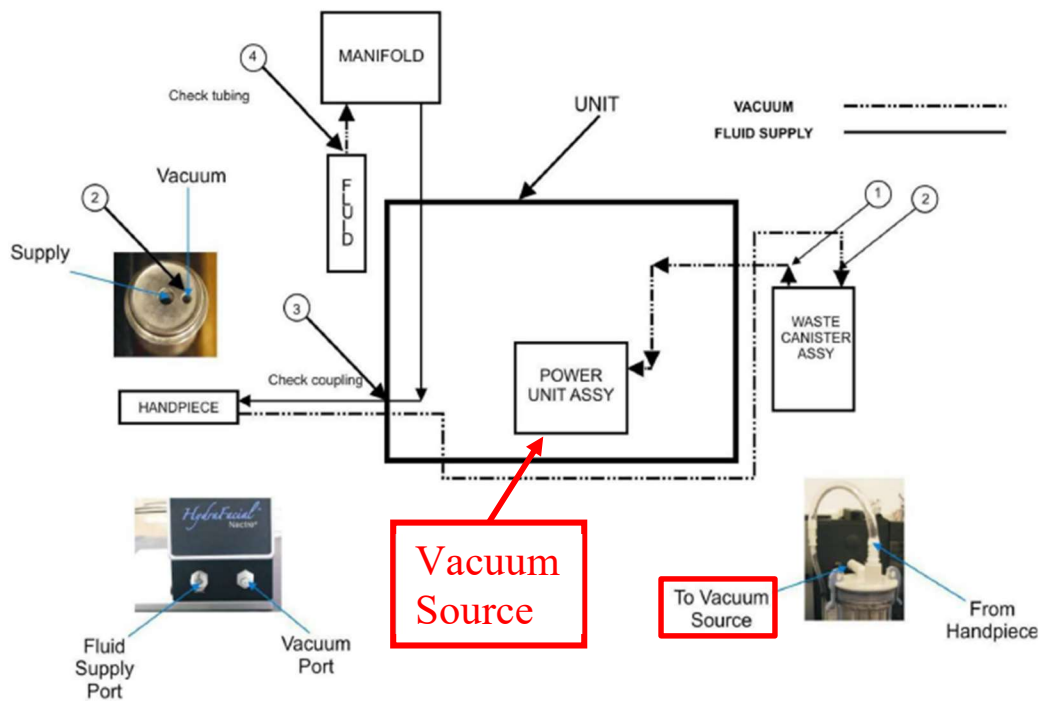
Increase vacuum level by gliding



Increase vacuum level by tapping

Ex. 2036 at 18 (Nectre User Manual).

222. As shown in the schematic and image below, the Nectre includes a vacuum source.

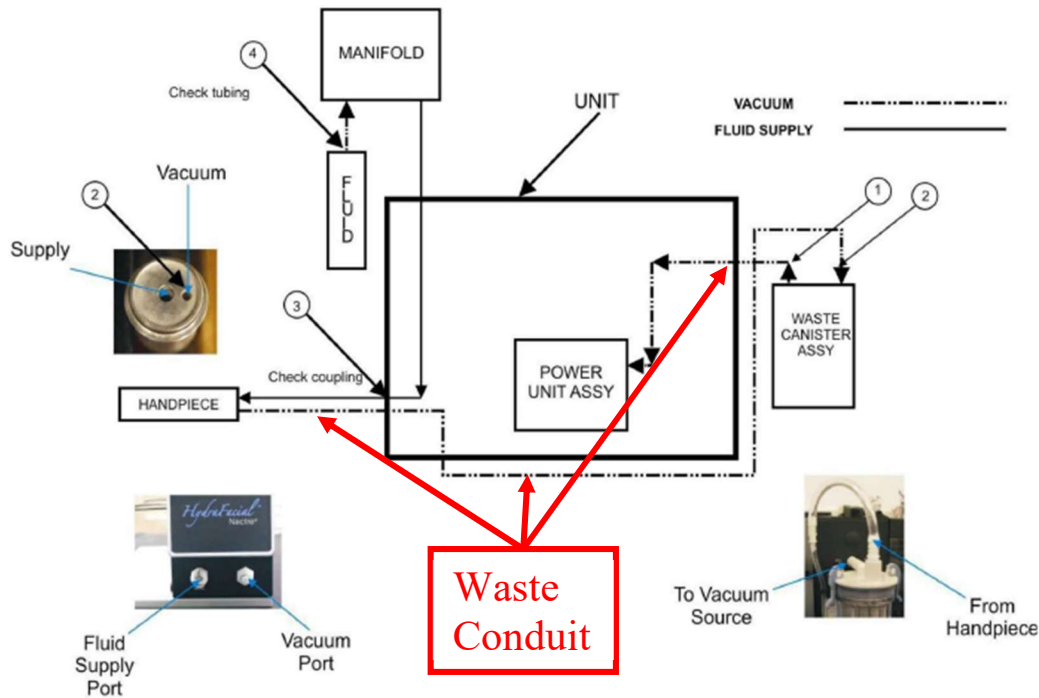


Ex. 2037 at 6 (Nectre Service Manual).

- g. **“a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and”**

223. In my opinion, the HydraFacial Nectre has “a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source.”

224. As shown in the schematic and image below, a waste conduit places the tip of the handpiece assembly in fluid communication with the vacuum source.



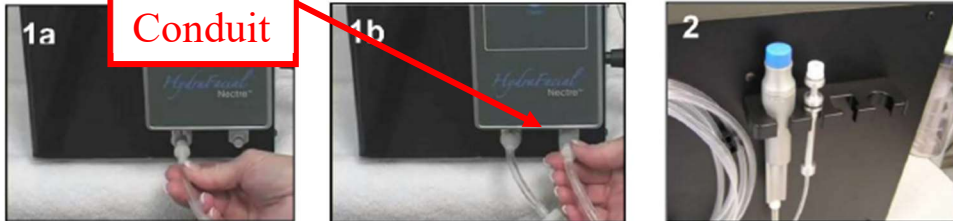
Ex. 2037 at 6 (Nectre Service Manual).

225. The image above shows a “vacuum port” where tubing from the handpiece assembly connects to the console (the tubing containing the waste conduit). The image above also shows tubing entering the waste container (“from handpiece”) and tubing leaving the waste container (“to vacuum source”) that contains the waste conduit.

226. The Nectre Owner’s Manual instructs a user to connect the “handpiece tubing” (containing part of the waste conduit) to the console of the Nectre. Because the handpiece tubing (waste conduit) is connected to the handpiece, the waste conduit is in fluid communication with the tip of the handpiece assembly.

3) INSTALL THE HYDRAFACIAL HANDPIECE

1. Connect the quick disconnect fittings on the handpiece tubing to the corresponding fittings on the front of the machine. You will hear a click when they are securely attached.
2. Place the handpiece into the tool holder on the right side of the unit.
3. Always **Waste Conduit** in the tool holder when the handpiece is not in use.



Ex. 2035 at 13 (Nectre Owner's Manual).

227. The waste conduit is used to remove waste away from the skin of a subject during a skin treatment procedure. One of the User Manual's solutions for troubleshooting "no or low fluid low" is to:

11. Check level of liquid in waste container. If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. If this happens, empty the waste container. The cone-shaped float on the lid will return to normal position allowing the resumption of skin solution flow. If the float does not return to normal position, use your finger to gently loosen it and return it to the normal position.

Ex. 2036 at 21 (Nectre User Manual).

228. Because the waste container blocks the vacuum opening on the handpiece assembly when the waste container is too full, the waste conduit is in fluid communication with the handpiece assembly, and thus, the tip of the handpiece assembly.

- h. "wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be**

delivered through the supply conduit to the handpiece assembly; and”

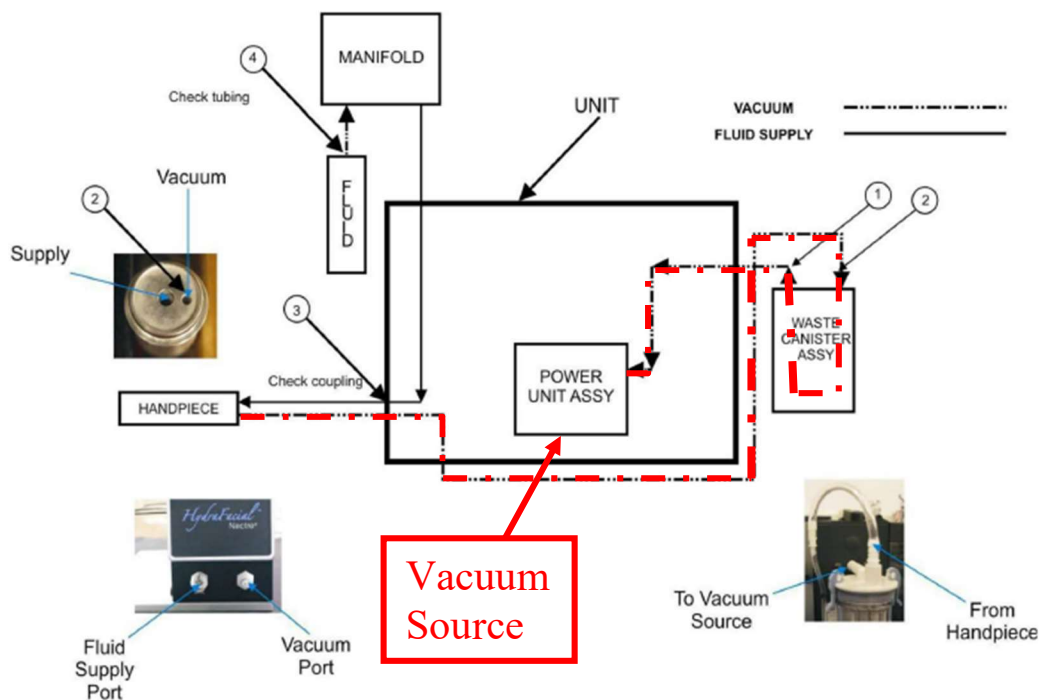
229. The HydraFacial Nectre is not “configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.” A user must disconnect the single connected fluid container for a different container to select a treatment material from a different container for delivery to the handpiece assembly.

- i. **“wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.”**

230. In my opinion, the HydraFacial Nectre has a vacuum source, that when “activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.”

231. As explained above, the HydraFacial Nectre has (1) a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, (2) a vacuum source operatively coupled to the waste conduit, (3) a handpiece assembly with a tip

that is configured to contact a skin surface of a subject during treatment, and (4) a block component where a fluid container connects configured to control a flow of treatment material from the attached fluid container through the supply conduit to the handpiece assembly. *See* sections VII.C.1.c, d, e, and g, *supra*. As shown below, it is the same suction force that removes waste from the skin surface via the waste conduit that also draws treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.



Ex. 2037 at 6 (Nectre service Manual).

232. The “Troubleshooting” section of the Nectre User Manual and Nectre Owner’s Manual warns that, “[i]f the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will

cease.” Ex. 2036 at 21 (Nectre User Manual); Ex. 2035 at 20 (Nectre Owner’s Manual). The recommended solution to this situation is to “empty the waste container.” *Id.* Thus, the vacuum draws from the connected fluid container to the handpiece assembly when the tip is pressed against skin.

11. Check level of liquid in waste container. If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. If this happens, empty the waste container. The cone-shaped float on the lid will return to normal position allowing the resumption of skin solution flow. If the float does not return to normal position, use your finger to gently loosen it and return it to the normal position.

Ex. 2036 at 21 (Nectre User Manual); Ex. 2035 at 20 (Nectre Owner’s Manual).

233. For all of these reasons, it is my opinion the Nectre meets the limitations of Claim 1 of the ’052 Patent literally or under the doctrine of equivalents, with the exception of limitations directed to having a manifold in fluid communication with multiple containers that contain a liquid treatment material.

234. For the same reasons (e.g. that only a single container connects to the console), it is my opinion that the Nectre does not practice every element of claims 1-17.

2. Nexus Between the HydraFacial System’s Commercial Success and ’052 Patent Claims

235. In my opinion, the difference between the Syndeo, Elite, Allegro, and Tower Systems, and the Nectre is the multi-container hydrodermabrasion system (having a manifold of a console, waste conduit, and waste container) found in the

Syndeo, Elite, Allegro, and Tower, as opposed to the single-container hydrodermabrasion system found in the Nectre.

236. It is further my opinion that the multi-container system allows for easier and more efficient facials (no need to pause treatment to change bottles), making the Syndeo, Elite, Allegro, and Tower more desirable. This is confirmed by the poor sales of the Nectre compared to the multi-container systems, and I understand the poor sales led to the Nectre being discontinued. *See* Ex. 2009 (Declaration of Vipul Savsani) at ¶¶ 7-8. Except for using only a single container at a time in a treatment, the Nectre is comparable in every other material respect to the other multi-container HydraFacial Systems and had the same ability to use the same treatment solutions and the handpiece tips.

237. Accordingly, it is my opinion that there is a nexus between the commercial success of the HydraFacial Systems and the claims of the '052 Patent directed to a multi-container system.